

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
11 January 2007 (11.01.2007)

PCT

(10) International Publication Number
WO 2007/005585 A2

(51) International Patent Classification:

A61B 17/00 (2006.01) *A61B 17/064* (2006.01)
A61B 17/068 (2006.01) *A61B 17/122* (2006.01)

(74) Agents: **RICHARDS, Jonathan, W. et al.**; **WORKMAN NYDEGGER**, 1000 EAGLE GATE TOWER, 60 East South Temple, Salt Lake City, UT 84111 (US).

(21) International Application Number:

PCT/US2006/025538

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(22) International Filing Date:

29 June 2006 (29.06.2006)

(25) Filing Language:

English

(26) Publication Language:

English

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SI, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(30) Priority Data:

60/696,069 1 July 2005 (01.07.2005) US
11/427,297 28 June 2006 (28.06.2006) US

(71) Applicant (for all designated States except US): **ABBOTT LABORATORIES** [US/US]; 400 Saginaw Drive, Redwood City, CA 94063 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **WALBERG, Erik, K.** [US/US]; 1901 Terry Lane, Redwood City, CA 94061 (US). **REYNOLDS, Timothy, C.** [US/US]; 608 Conrado Terrace #3, Sunnyvale, CA 94085 (US). **ELLINGWOOD, Brian, A.** [US/US]; Po Box 60113, Sunnyvale, CA 95051 (US). **JAIR, Kai, Yenkai** [US/US]; 7100 Rainbow Drive #14, San Jose, CA 95129 (US). **PANTAGES, Anthony** [US/US]; 1839 Curtner Avenue, San Jose, CA 95124 (US).

Published:

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 2007/005585 A2

(54) Title: CLIP APPLIER AND METHOD OF USE

(57) Abstract: An apparatus for placement into an opening formed in a wall of a body lumen to deploy a closure element. The apparatus comprising a housing having a handle portion formed at a distal end, the handle portion configured to be engaged by a user when advancing the housing to deploy the closure element. A locator assembly and a carrier assembly are at least partially received in the housing. The locator assembly can have one or more expansion members that can selectively contact the wall of the body lumen and a proximal end configured to cooperate with a portion of a locator control system operable to expand the one or more expansion members. A triggering system cooperates with the locator assembly and is moveable toward the one or more expansion members of the locator assembly upon the locator control system being operated to expand the one or more expansion members.

1
CLIP APPLIER AND METHODS OF USEFIELD OF THE INVENTION

The present invention relates generally to apparatus and methods for closing and/or sealing openings through tissue, and more particularly to apparatus and methods for 5 delivering a closure element for closing a puncture in a blood vessel or other body lumen formed during a diagnostic or therapeutic procedure.

BACKGROUND OF THE INVENTION

Catheterization and interventional procedures, such as angioplasty or stenting, generally 10 are performed by inserting a hollow needle through a patient's skin and tissue into the vascular system. A guide wire may be advanced through the needle and into the patients blood vessel accessed by the needle. The needle is then removed, enabling an introducer sheath to be advanced over the guide wire into the vessel, e.g., in conjunction with or subsequent to a dilator.

A catheter or other device may then be advanced through a lumen of the introducer sheath 15 and over the guide wire into a position for performing a medical procedure. Thus, the introducer sheath may facilitate introducing various devices into the vessel, while minimizing trauma to the vessel wall and/or minimizing blood loss during a procedure.

Upon completing the procedure, the devices and introducer sheath would be removed, leaving a puncture site in the vessel wall. Traditionally, external pressure would be 20 applied to the puncture site until clotting and wound sealing occur, however, the patient must remain bedridden for a substantial period of time after clotting to ensure closure of the wound. This procedure, however, may be time consuming and expensive, requiring as much as an hour of a physicians or nurses time. It is also uncomfortable for the patient, and requires that the patient remain immobilized in the operating room, catheter 25 lab, or holding area. In addition, a risk of hematoma exists from bleeding before hemostasis occurs.

Various apparatus have been suggested for percutaneously sealing a vascular puncture by 30 occluding the puncture site. For example, U.S. Patent Nos. 5,192,302 and 5,222,974, issued to Kensey et al., describe the use of a biodegradable plug that may be delivered through an introducer sheath into a puncture site. Another technique has been suggested that involves percutaneously suturing the puncture site, such as that disclosed in U.S. Patent No. 5,304,184, issued to Hathaway et al.

To facilitate positioning devices that are percutaneously inserted into a blood vessel, "bleed back" indicators have been suggested. For example, U.S. Patent No. 5,676,974,

issued to Kensey et al., discloses a bleed back lumen intended to facilitate positioning of a biodegradable plug within a puncture site. This device, however, requires that an anchor of the plug be positioned within the vessel, and therefore, may increase the risk of over-advancement of the plug itself into the vessel.

5 Alternatively, U.S. Patent No. 5,674,231, issued to Green et al., discloses a deployable loop that may be advanced through a sheath into a vessel. The loop is intended to resiliently expand to engage the inner wall of the vessel, thereby facilitating holding the sheath in a desired location with respect to the vessel.

Accordingly, apparatus and methods for delivering a device for closing a vascular 10 puncture site or other opening through tissue would be useful.

BRIEF SUMMARY

The present invention is directed toward an apparatus and method for delivering a closure element through tissue and into an opening formed in, or adjacent to, a wall of a blood vessel or other body lumen of any size. The apparatus can be configured to receive and 15 retain the closure element so that the closure element can be disposed substantially within the apparatus. Thereby, when the apparatus is introduced via an introducer sheath, for example, the closure element can be disposed within and delivered by way of a lumen of the introducer sheath. The apparatus can also be configured to engage the blood vessel wall adjacent to the opening and to position the closure element substantially adjacent to 20 an outer surface of the blood vessel wall adjacent to the opening.

When properly positioned, the apparatus can be activated to distally deploy the closure element. During deployment, the apparatus can be configured to substantially uniformly expand the closure element beyond a natural cross-section of the closure element such that the closure element, when deployed, can be configured to engage the blood vessel 25 wall and/or tissue. Engaging the blood vessel wall and/or tissue, the closure element can be further configured to return to the natural cross-section. Thereby, the engaged blood vessel wall and/or tissue are drawn substantially closed and/or sealed, such that, for example, hemostasis within the opening can be enhanced.

The present invention can also accommodate for variations in the size of the physician's 30 hand and grip by selectively reducing the distance between the device's handle portion and a portion of a triggering system usable to deploy the closure element. The triggering system of the apparatus can at least partially move a trigger extension graspable by a physician or clinician as a locator assembly locates the blood vessel wall prior to deploying the closure element. This partial movement reduces the gap between the

trigger extension and the handle portion. In this manner, a physician or clinician does not need to stretch uncomfortably to position a thumb or finger on the trigger extension, grasping the handle portion, and maintaining the device in the desired orientation relative to the tissue and/or the puncture site.

5 An apparatus of the present invention is usable to deliver a closure element to an opening formed in a wall of a body lumen. The apparatus can include a locator assembly having a distal end region configured to extend into the opening and selectively contact the wall of the body lumen and a proximal end configured to cooperate with a movable plunger. A carrier assembly can be coupled with the locating assembly, the carrier assembly retaining the closure element in a substantially tubular configuration within the carrier assembly. A triggering system can also cooperate with the locator assembly, the triggering system can move toward the distal end region of the locator assembly as the movable plunger moves toward the distal end region. In one configuration, the triggering system can move toward the distal end region substantially simultaneously with the distal 10 end region transitioning from the unexpanded state to the expanded state.

15 The locator assembly of the apparatus can further include a locator control system coupled to a proximal end region of the locator assembly. This locator control system can be configured to selectively control the distal end region of the locator assembly between the expanded state and the unexpanded state. In one configuration, the locator control system can include a tubular body block mounted to a tubular member, a spring retainer receiving a portion of the tubular body block, and a movable plunger slidably cooperating with the tubular body block and the tubular member.

20 The present invention can also provide a stable base upon which the physician or clinician can move the device or apparatus as the closure element is positioned and deployed. In one configuration, the stable base is formed from the handle portion having two graspable portions: a shaped grasping portion and an elongated grasping portion. The shaped grasping portion can be configured to receive at least a thumb or finger of the physician. A portion of the handle portion can have a curved profile to enable a portion of the handle to fit comfortably within a user's hand while the hand is rested on a patient during the 25 procedure to provide stability during use of the device and function as a based or pivot point for moving the remainder of the device or apparatus.

30 Other aspects and features of the present invention will become apparent from consideration of the following description in conjunction with the accompanying drawings.

⁴
BRIEF DESCRIPTION OF THE DRAWINGS

In order to describe the manner in which the above-recited and other advantages and features of the invention can be obtained, a more particular description of the invention briefly described above will be rendered by reference to specific embodiments thereof

5 which are illustrated in the appended drawings. Understanding that these drawings depict only typical embodiments of the invention and are not therefore to be considered to be limiting of its scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings.

Fig. 1A illustrates an assembly view of the components of one embodiment according to
10 the present invention for closing openings in blood vessel walls.

Fig. 1B illustrates another assembly view of the components of one embodiment according to the present invention for closing openings in blood vessel walls.

Fig. 2 illustrates the assembled carrier assembly and triggering assembly of the apparatus shown in Figs. 1A and 1B.

15 Fig. 3A illustrates a close-up view of the proximal end of the apparatus shown in Fig. 2.

Fig. 3B illustrates a close-up view of the distal end of the apparatus shown in Fig. 2 in an unexpanded state.

Fig. 3C illustrates a close-up view of the distal end of the apparatus shown in Fig. 2 in an expanded state.

20 Fig. 4 illustrates the apparatus of Fig. 2 after distal advancement of the locator assembly, the triggering system and the carrier assembly.

Fig. 5 illustrates a close-up view of the triggering system and carrier assembly of the apparatus shown in Fig. 4.

Fig. 6 illustrates the apparatus of Fig. 1A-1B after the clip has been released to close the
25 opening in the tissue.

Fig. 7 illustrates a close-up view of the triggering system and carrier assembly of the apparatus of Fig. 1A-1B after the clip has been released to close the opening in the tissue.

Fig. 8 illustrates a cross-sectional schematic view of the distal end of the apparatus shown in Fig. 4 as assembled for deployment.

30 Fig. 9 illustrates a plan view of an alternative embodiment of an apparatus for closing openings in tissue in accordance with the present invention.

Fig. 10 illustrates a portion of a housing half of the alternative embodiment of Fig. 9, illustrating the functional components thereof.

5 Fig. 11A illustrates a portion of a housing half of the alternative embodiment of Fig. 9, without certain functional components.

Fig. 11B illustrates a portion of a locator control system of the alternative embodiment of Fig. 9.

5 Fig. 11C illustrates a portion of a locator release system of the alternative embodiment of Fig. 9.

Fig. 11D illustrates a side view of a plunger of the locator control system of Fig. 11B of the alternative embodiment of Fig. 9.

10 Fig. 11E illustrates a perspective view of a tubular body block of the locator control system of Fig. 11B of the alternative embodiment of Fig. 9.

Fig. 11F illustrates a perspective view of a spring retainer of the locator control system of Fig. 11B of the alternative embodiment of Fig. 9.

Fig. 12 illustrates a close-up cross-sectional view of the proximal end of the apparatus shown in Fig. 9, illustrating the initial position of the locator control system.

15 Fig. 13 illustrates a close-up cross-sectional view of the proximal end of the apparatus shown in Fig. 9, illustrating the final position before clip release of the locator control system.

Figs. 14A-14G illustrate various embodiments of closure elements that can be utilized with the apparatus of the present invention.

20 Figs. 15A-K illustrate various steps in the deployment of embodiments of the present invention.

It should be noted that the figures are not drawn to scale and that elements of similar structures or functions are generally represented by like reference numerals for illustrative purposes throughout the figures. It also should be noted that the figures are only intended 25 to facilitate the description of embodiments of the present invention.

DETAILED DESCRIPTION

The embodiments described herein extend to methods, systems, and apparatus for closing and/or sealing openings in a blood vessel or other body lumen formed during a diagnostic or therapeutic procedure. The apparatuses of the present invention are configured to 30 deliver a closure element through tissue and into an opening formed in and/or adjacent to a wall of a blood vessel or other body lumen.

Since current apparatuses for sealing openings formed in blood vessel walls can snag tissue adjacent to the openings during positioning and may not provide an adequate seal, an apparatus that is configured to prevent inadvertent tissue contact during positioning

and to engage tissue adjacent to the opening can prove much more desirable and provide a basis for a wide range of medical applications, such as diagnostic and/or therapeutic procedures involving blood vessels or other body lumens of any size. Further, since current apparatuses for sealing openings formed in blood vessel walls are typically one-size and do not provide a mechanism to accommodate for variations in the size or configuration of the physician or clinicians hands, an apparatus that varies its operational configuration to accommodate for physician or clinician hand sizes can prove much more desirable and beneficial to the medical arts. These results, whether individually or collectively, can be achieved, according to one embodiment of the present invention, by employing an apparatus as shown in the figures and described in detail below.

As will be discussed in more detail below, the apparatuses of the present invention are configured to deliver a closure element through tissue and into an opening formed in and/or adjacent to a wall of a blood vessel or other body lumen. The apparatus can be configured to receive and retain a closure element such that the closure element can be disposed substantially within the apparatus. The apparatuses in accordance with the present invention generally include a handle portion having a proximal end and a distal end, a locator and clip delivery assembly extending from the distal end of the handle portion, and a locator actuator disposed at the proximal end of the handle portion.

Referring now to Fig. 1, an exploded assembly view of one closure apparatus is shown in accordance with the present invention. As shown in Fig. 1, the apparatus can include a housing that receives or retains a plurality of tubular members. The tubular members can be concentrically disposed within the housing of the device, with each tubular member having an associated block member fixedly attached to the proximal end thereof. The block members can be configured to interact with each other as well as with features of the housing, such as through movement of a triggering system. The interaction of the tubular members, the blocks, and the triggering system will be described in greater detail below. Also described below will be additional details regarding the handle portion of the housing and the manner by which the movement of the tubular members and the triggering system results in variation of the devices operational configuration to accommodate for physician or clinician hand sizes.

With continued reference to Figs. 1A and 1B, apparatus 100 can be provided as one or more integrated components and/or discrete components that may be retained within a housing 102, having a housing top half 380c and a housing bottom half 380d (not shown). For example, apparatus 100 can include a locator assembly 110 and a carrier assembly

120. For purposes of illustration, locator assembly 110 and carrier assembly 120 are shown in Fig. 1A as comprising substantially separate assemblies. As desired, however, locator assembly 110 and carrier assembly 120 each can be provided, in whole or in part, as one or more integrated assemblies.

- 5 Turning to Figs. 1A-2, 4, and 6, the assembly 110 can include a locator assembly 200. This locator assembly 200 can include flexible or semi-rigid tubular body 210 (such as an elongate rail) with a longitudinal axis. Tubular body 210 can have a proximal end region 210a and a distal end region 210b and can include a predetermined length and a predetermined outer cross-section, both of which can be of any suitable dimension.
- 10 Distal end region 210b of locator assembly 200, as shown in more detail in Figs. 3B and 3C, can include a substantially rounded, soft, and/or flexible distal end or tip 220 to facilitate advancement and/or retraction of distal end region 210b into a blood vessel or other opening in tissue. As desired, a pigtail (not shown) may be provided on tip 220 to further aid atraumatic advancement of distal end region 210b.
- 15 Distal end region 210b of locator assembly 200 is selectively controllable between an unexpanded state, as shown in Fig. 3B, and an expanded state, as shown in Fig. 3C. As shown in Fig. 3B, when an expansion end 230 is in an unexpanded state, substantially flexible members 232 are substantially axially aligned with locator assembly 200. Alternatively, when expansion end 230 is in an expanded state, substantially flexible members 232 are flexed outward.
- 20

Returning to Figure 1B, a control member 250, such as a rod, wire, or other elongate member, may be moveably disposed within a lumen (not shown) formed by tubular body 210 and extending substantially between the proximal end region 210a and distal end region 210b. Control member 250 may have proximal end region 250a coupled with a control block 260, and a distal end region 250b coupled with distal end region 210b of locator assembly 200, expansion end 230, and/or the movable end regions of substantially flexible members 232. Control block 260 may be formed of a metal or rigid plastic in a tubular shape, and may be adapted to be retained in control block cavity 265 formed on the internal surface of housing bottom half 380d, to thereby maintain control block 260 in a substantially fixed position relative to the housing 380. By moving tubular body 210 axially relative to control member 250, the distal end region 210b, expansion end 230, and/or the substantially flexible members 232 (Fig. 3B), are selectively transitioned between the unexpanded and expanded states.

With reference to Figure 3A, a tubular body block 270 having proximal groove 271 may be formed on proximal end 210a of tubular body 210. Tubular body block 270 may be formed of metal, rigid plastic, or other substantially rigid material and may be formed integrally with or attached securely to tubular body 210. Proximal groove 271 and the proximal end of tubular body block 270 may have a shape adapted to cooperate with a pair of tabs 279a, 279b formed on a locator assembly block 280, whereby tubular body block 270 may be maintained in a fixed axial relationship with the locator assembly block 280. In this way, tubular body block 270 and tubular body 210 (Fig. 1B) may advance distally by distal advancement of locator assembly block 280.

10 A locator assembly spring 290 may be located coaxially with and may substantially surround a portion of tubular body block 270. Locator assembly spring 290 may be located between and in contact with the distal side of two of tabs 279a, 279b formed on locator assembly block 280 and the proximal side of locator assembly spring stop 381 formed on the inner surface of housing bottom half 380d. The locator assembly spring 290 so located may provide a force biasing to locator assembly block 280 in the proximal direction relative to housing 380.

Locator assembly block 280 may be formed of metal, plastic, or other rigid material. A function of locator assembly block 280 may be to allow a user to apply a force causing distal movement of tubular body 210 (Fig. 1) relative to control member 250 causing locator assembly 200 (Fig. 2) to transition from the unexpanded state to the expanded state. Slot 281 may be formed in the proximal end of locator assembly block 280. Slot 281 may have a size sufficient to accommodate control block 260 and control block cavity 265, and to allow locator assembly block 280 to travel axially relative to housing 380. As shown in Fig. 1, the distal end of locator assembly block 280 may include a pair of distally extending legs 282a-b, with each of legs 282a-b having a ramp 283a-b on its inward facing surface. Finally, the locator assembly block 280 may have a pair of distally extending release tabs 284a-b, each of release tabs 284a-b having a detent 285a-b.

As shown in Figs. 2-3A, locator assembly block 280 may be slidably received and retained within grooves formed in the proximal end of housing 380, with the proximal end of locator assembly block 280 extending from the proximal end of housing 380. Control block 260 and control block cavity 265 may be located in slot 281 formed in the proximal end of locator assembly block 280.

To release locator assembly 200, and enable it to slidably move within the grooves formed in the proximal end of the housing 380 and allow locator assembly 200 to

transition from its expanded state to its unexpanded state, the apparatus 100 can include a locator release system 490 (Fig. 1A). Turning to Fig. 1A, locator release system 490 of the apparatus 100 may include locator release rod 491 having release tab spacer block 492 formed on its proximal end. Locator release rod 491 and release tab spacer block 492 5 may be received and retained in a groove formed on the interior surface of housing bottom half 380d. Release tab spacer block 492 may be integrally formed with or attached to the proximal end of locator release rod 491 and may be formed of metal, plastic, or other rigid material. Release tab spacer block 492 may have a shape and size adapted to fit between release tabs 284a-b formed on locator assembly block 280, thereby 10 biasing release tabs 284a-b outward and causing outward facing detents 285a-b to engage retaining grooves 286a-b (Fig. 1B) formed on the interior of housing 380. As long as detents 285a-b are thus engaged with retaining grooves 286a-b in housing 380, locator assembly block 280 is held in an axial position against the spring force imparted in the proximal direction by locator assembly spring 290.

15 With continued reference to Fig. 1A, the distal end of locator release rod 491 may have an engagement member 493 that comprises an inward bend on the distal end of locator release rod 491. As described more fully below, engagement member 493 on locator release rod 491 may be positioned within the apparatus 100 such that when closure element 500 is delivered, engagement member 493 is engaged and caused to move axially 20 in the distal direction, thereby disengaging release tab spacer block 492 from locator assembly block 280 and causing locator assembly 200 simultaneously to transition from an expanded state to an unexpanded state.

Returning to Fig. 1A, the carrier assembly 120 may be coupled with, and slidable relative 25 to, locator assembly 200. Carrier assembly 120 may be configured to receive and retain closure element 500, which may be disposed substantially within carrier assembly 120. Carrier assembly 120 may be further configured to position closure element 500 substantially adjacent to an opening to be closed, and to deploy closure element 500. Upon being deployed, closure element 500 can maintain a reduced cross-section but may also temporarily and substantially uniformly expand beyond the natural cross-section of 30 closure element 500. In either case, closure element 500, when deployed, can engage an amount of the blood vessel wall and/or tissue adjacent to the opening. Thereafter, closure element 500 may be configured to return to the natural cross-section, optionally substantially uniformly, such that the blood vessel wall and/or tissue are drawn substantially closed and/or sealed.

As shown in Fig. 1A, carrier assembly 120 may include a tube set 305 of at least one tubular member. For instance, the illustrated tube set can include carrier member 310, pusher member 320, cover member 330, and support member 340, also shown in Fig. 8. Carrier member 310, pusher member 320, cover member 330, and support member 340 5 may be provided as a plurality of nested, telescoping members with a common longitudinal axis. Carrier member 310 may be configured to receive and support closure element 500. While being disposed on carrier member 310, closure element 500 may be deformed from the natural, planar configuration to form a substantially tubular closure element 500", as shown in Figs. 14A-14G, and as described herein.

10 Returning to Fig. 1A, carrier member 310 may include proximal end region 310a and distal end region 310b. Carrier member 310 may also define lumen 314, which may extend substantially between proximal end region 310a and distal end region 310b and configured to slidably receive at least a portion of tubular body 210 of locator assembly 200 and/or support member 340. Although the exterior cross-section of the carrier member 310 may be substantially uniform, the distal end region 310b of carrier member 310 may have a cross-section that increases distally, as illustrated in Fig. 1A, for substantially uniformly expanding substantially tubular closure element 500 (Fig. 14G) beyond natural cross-section 530 (Fig. 14A) of closure element 500" when substantially tubular closure element 500" is deployed. Alternatively, distal end region 310b may be 15 formed with a uniform cross-section to deploy closure element 500 without cross-sectional expansion.

20

Pusher member 320 may have proximal end region 320a and distal end region 320b. Pusher member 320 may be coupled with, and slidably relative to, carrier member 310. Pusher member 320 may include a predetermined length and a predetermined cross-section, both of which can be of any suitable dimension and can be configured to slidably receive carrier member 310 such that distal end region 320b of pusher member 320 may be offset proximally from distal end region 310b of carrier member 310. As desired, the predetermined length of pusher member 320 may be substantially equal to a predetermined length of carrier member 310. A predetermined length of pusher member 320 may be less than a predetermined length of carrier member 310 such that carrier member 310 and pusher member 320 may at least partially define a space 360 (Fig. 8) 25 distal to distal end region 320b of pusher member 320 and along the periphery of carrier member 310.

Pusher member 320 may be substantially ¹¹tubular and can define a lumen 324 that may extend substantially between proximal end region 320a and distal end region 320b and configured to slidably receive at least a portion of the carrier member 310. The cross-section of pusher member 320 may be substantially uniform and distal end region 320b of pusher member 320 can comprise one or more longitudinal extensions 325, which may extend distally from pusher member 320 and along the periphery of carrier member 310. Longitudinal extensions 325 may be biased such that longitudinal extensions 325 extend generally in parallel with the common longitudinal axis of carrier assembly 120. Longitudinal extensions 325 may be sufficiently flexible to expand radially, and yet 10 sufficiently rigid to inhibit buckling as distal end region 320b is directed distally along carrier member 310 and engages the distally-increasing cross-section of distal end region 310b of carrier member 310 to deploy closure element 500

Cover member 330 may be configured to retain closure element 500, in its generally tubular configuration, substantially within the carrier assembly 120 prior to deployment. 15 Being coupled with, and slidable relative to, pusher member 320, cover member 330 has proximal end region 330a and distal end region 330b, a predetermined length and a predetermined cross-section, both of which can be of any suitable dimension. Cover member 330 may be formed as a substantially rigid, semi-rigid, or flexible tubular member with an inner periphery and an outer periphery, and may define a lumen 334. 20 Lumen 334 may extends substantially between proximal and distal end regions 330a, 330b of cover member 330 and may be configured to slidably receive at least a portion of pusher member 320. When cover member 330 is properly positioned within carrier assembly 120, as schematically illustrated in Fig. 15A, distal end region 330b may be configured to extend over the space 360, thereby defining annular cavity 370 for receiving and retaining substantially tubular closure element 500". 25

The cross-section of cover member 330 may be substantially uniform, and distal end region 330b of cover member 330 may comprise one or more longitudinal extensions 335, which extend distally from cover member 330 and along an outer periphery of pusher member 320, as shown in Fig. 8. Although longitudinal extensions 335 can 30 extend generally in parallel with the longitudinal axis of the tube set 305, longitudinal extensions 335 may be biased such that the plurality of longitudinal extensions 335 extend substantially radially inward. Thereby, longitudinal extensions 335 may at least partially close lumen 334 substantially adjacent to distal end region 330b of cover member 330.

With reference to Fig. 1B and 15A, to permit closure element 500 to be deployed from annular cavity 370, longitudinal extensions 335 may be sufficiently flexible to expand radially to permit distal end region 310b of carrier member 310 to move distally past cover member 330 to open annular cavity 370 such that distal end region 330b no longer extends over the space 360.

When carrier assembly 120 is assembled as a plurality of nested, telescoping members, as shown in Figs. 2 and 8, carrier member 310 is at least partially disposed within, and slidably relative to, a lumen of pusher member 320, and support member 340 is slidably relative to pusher member 310. Pusher member 320, in turn, is at least partially disposed within, and slidably relative to, lumen 334 of cover member 330. To couple carrier assembly 120 with locator assembly 200, tubular body 210 of locator assembly 200 may be at least partially disposed within, and slidably relative to, lumen 314. The longitudinal axis of locator assembly 200 may be substantially in axial alignment with the common longitudinal axis of carrier member 310, pusher member 320, and cover member 330.

The apparatus 100 may also include support member 340 as shown in Fig. 1A. Support member 340 may be configured to slidably receive tubular body 210 of locator assembly 200 and provide radial support for distal end region 210b of tubular body 210 when locator assembly 200 is coupled with the carrier assembly 120. Carrier assembly 120 can advantageously include support member 340, for example, if tubular body 210 is not sufficiently rigid or under other circumstances in which support for tubular body 210 might be desirable. It also will be appreciated that support member 340 may also be configured to inhibit longitudinal extensions 335, which extend from distal end region 330b of cover member 330, from expanding prematurely when closure element 500 is deployed. If longitudinal extensions 335 were to expand prematurely, they may become hung up on an introducer sheath or other delivery member (if an introducer sheath or delivery member is used), the tissue, or the wall of the blood vessel. This may interfere with the proper advancement or other movement of cover member 330 and carrier assembly 120.

Support member 340 may be formed as a substantially rigid, semi-rigid, or flexible tubular member, and may include proximal end region 340a and distal end region 340b. Having an outer periphery, support member 340 may define lumen 344, extending substantially between proximal end region 340a and distal end region 340b and configured to slidably receive and support at least a portion of tubular body 210 of locator assembly 200. Support member 340, in turn, can be at least partially slidably disposed

within lumen 314 of carrier member 310 such that tubular body 210 of locator assembly 200 is coupled with, and slidably relative to, carrier member 310 in the manner described in more detail above. ¹³

Support member 340 may have a predetermined length and a predetermined cross-section, both of which can be of any suitable dimension, and may have a substantially uniform cross-section. Although shown and described as being substantially separate for purposes of illustration, it will be appreciated that carrier member 310, pusher member 320, cover member 330, and/or support member 340 may be provided, in whole or in part, as one or more integrated assemblies.

5 With reference to Fig. 8, support member 340 may also include a distal end that is blunt, rounded and/or includes a radius or curved portion that may prevent and/or eliminate damage to tubular body 200 as tubular body is moved with respect to support member 340. In some cases during deployment, as discussed in more detail below, tubular body 200 may be inserted into a lumen of an introducer at such an angle as to require tubular body 200 to flex with respect to tube set 305 as much as between about 0 degrees and 90 degrees, preferably between about 10 degrees and 90 degrees and more preferably between 30 degrees and 60 degrees, for example when used in conjunction with a femoral artery. The above-described distal end of the distal end region 340b prevents and/or eliminates damage to tubular body 200 that may result from a sharp edge pressed along tubular body 200 during advancement of tube set 305, and more particularly, support member 340 and the distal end of the distal end region 340b.

10

15

20

Illustratively, the radii of the distal end of the support member 340 can have various sizes and configurations. In one configuration, the distal end radii can be about 0.002 inches. In still another configuration, the distal end radii can be about 0.004 inches. In still another configuration, the distal end radii can be about 0.002 inches or greater. Increasing the radii of the distal end of support member 340 to about 0.004 inches, for instance, can decrease the amount of force required to overcome a bend in locator assembly 200 over those devices having a distal end radii of about 0.002 inches. This is because a gap formed between the interior diameter of support member 340 and the locator assembly 200 is larger for the 0.004 inch radii than for the 0.002 inch radii.

25

30

In addition to the above, with the distal end having a radii greater than 0.002 inches, such as but not limited to 0.004 inches, there is a decrease in the possibility that the support member 340 cuts or otherwise damages the locator assembly 200 during positioning of the distal end of the apparatus 100 and subsequent deployment of the closure element

500. Further, a radii greater than 0.002 inches, such as but not limited to 0.004 inches, may not increase the forces used to split an introducer sheath and may not elongate the introducer sheath during positioning and deploying of the closure element 500.

With reference to Figs. 1A and 1B, carrier assembly 120 may also include a portion of housing 380. For instance, the carrier assembly 120 can optionally include the top half 380c of housing 380, illustrated in Fig. 1A, and the bottom half 380d is shown in Fig. 1B. It will be understood, however, that housing 380 may be separate from the carrier assembly 120, while retaining and/or receiving all or a portion of the carrier assembly 120.

10 Housing 380 may be formed as an elongate member with a longitudinal axis, a periphery and may include proximal end region 380a and distal end region 380b. Thereby, when apparatus 100 is assembled, tubular body 210 of locator assembly 200 may be at least partially disposed within, and slidable relative to, tube set 305 such that distal end region 210b of tubular body 210 extends beyond distal end regions 310b, 320b, 330b, and/or 15 340b. Tubular body 210, carrier member 310, pusher member 320, cover member 330, and, if provided, support member 340 may be at least partially disposed within, and slidable relative to, housing 380. Proximal end region 210a of tubular body 210 and proximal end regions 310a, 320a, 330a, and/or 340a of tube set 305 can be at least 20 partially disposed within, and slidable relative to, housing 380. Distal end regions 210b, 310b, 320b, 330b, and 340b may extend from distal end region 380b of housing 380 such that common longitudinal axis 350 of tube set 305 may be substantially axially aligned with longitudinal axis 386 of housing 380. When configured to slidably retain respective proximal end regions 210a, 310a, 320a, 330a, and 340a, housing 380 supports tube set 305 and can have one or more handles 391, 392 to facilitate use of apparatus 100. 25 Handles 391, 392 may extend, optionally substantially radially, from the outer periphery of housing 380 and can be provided as illustrated or in any manner known in the art.

To facilitate deployment of the closure element 500, the apparatus 100 can include a triggering system 400, shown in Figure 2, which cooperates with a portion the locator assembly 200. For instance, a portion of locator assembly 200 and a portion of triggering system 400 may cooperate and be accessible externally to housing 380, as shown in Figs 30 1A and 1B. As shown in Figs. 1A, 1B, 4-7, triggering system 400 of apparatus 100 may be disposed substantially within housing 380. Triggering system 400 may be configured to control the relative axial movement and/or positioning of distal end regions 310b, 320b, 330b, and 340b and/or locator assembly distal end region 210b. Axial motion of

one or more of carrier member 310, pusher member 320, cover member 330, and support member 340 and/or tubular body 210 may be attained, for example, by applying an axial force to triggering extension 405.

Triggering system 400 may include a set of block members including carrier block 410, pusher block 420, cover block 430, and support block 440, each of which may be formed integrally with or securely attached to its respective member of carrier assembly 120. The block members may be adapted to selectively couple and decouple carrier member 310, pusher member 320, cover member 330, and support member 340 relative to one another in order to provide axial movement of those components in a predetermined manner intended to deliver closure element 500 in the manner described herein. For example, when carrier assembly 120 reaches a first predetermined distal position, support member 340 may be decoupled from carrier member 310, pusher member 320, and cover member 330, and may be thereafter substantially inhibited from further axial movement. Thereby, carrier member 310, pusher member 320, and cover member 330 may be directed distally as support member 340 remains substantially stationary. Subsequently, carrier member 310 and cover member 330 can be decoupled from pusher member 320 and thereby inhibited from further axial movement. Pusher member 320 may be directed distally as support member 340, carrier member 310, and cover member 330 remain substantially stationary, as described more fully herein.

Carrier block 410 may be disposed on proximal end region 310a of carrier member 310 and may include trigger extension 405, which extends through a slot in housing 380 to the exterior of housing 380, accessible by a user. This carrier block 410, as shown in Fig. 3A, may include a pair of grooves 413a-b formed on a peripheral surface of carrier block 410. Grooves 413a-b may be adapted to receive and retain a pair of tabs 445a-b formed on a pair of legs 444a-b extending distally from support block 440, thereby selectively coupling support block 440 to carrier block 410. Carrier block 410, as illustrated in Fig. 1A, may also include a pair of distal tabs 416a-b extending from the distal end of carrier block 410, and adapted to engage a pair of slots 423a-b formed on the proximal end of pusher block 420.

As shown in Figs. 1A and 3A, carrier block 410 may also include a pair of arms 414a-b extending in the proximal direction from the proximal end of carrier block 410, each of arm 414a-b having an outward directed tab 415a-b at its proximal end. Tabs 415a-b may be adapted to selectively engage a pair of slots 387a-b (Fig. 1B) formed on the interior surface of housing 380 near its proximal end and, when so engaged, to fix the axial

position of carrier block 410 and, with it, carrier assembly 120 relative to housing 380. Tabs 415a-b may be disengaged from slots 387a-b Fig. 1B) in housing 380 when locator assembly block 280 is moved axially in the distal direction in the following manner. As locator assembly block 280 is advanced distally, the interior surfaces of the ramps 283a-b 5 on locator assembly block legs 282a-b engage the exterior surfaces of tabs 415a-b and cause carrier block arms 414a-b to flex inward, releasing tabs 415a-b from the slots 387a-b in the housing, thereby freeing carrier block 410 and carrier assembly 120 to move axially. Thus, axial movement of carrier block 410 within apparatus 100 is inhibited until locator assembly block 280 is advanced to transition locator assembly 200 to the 10 expanded condition, simultaneously releasing tabs 415a-b on carrier block 410.

Pusher block 420 may be disposed on proximal end region 320a of pusher member 320. As described above, pusher block 420 may include a pair of slots 423a-b formed on its proximal end, and adapted to selectively engage distal tabs 416a-b extending from the distal end of carrier block 410. Pusher block 420 may also include a pair of grooves 15 424a-b formed on its peripheral surface, the grooves 424a-b being adapted to engage a pair of tabs 435a-b formed on a pair of forks 434a-b extending from the proximal side of cover block 430 to selectively couple cover block 430 to pusher block 420.

Cover block 430 may be disposed on proximal end region 330a of cover member 330. As described above, cover block 430 may include a pair of forks 434a-b extending from the 20 proximal end of the cover block 430, each of forks 434a-b having an inward directed tab 435a-b adapted to engage grooves 424a-b on the peripheral surface of pusher block 420 to selectively couple cover block 430 to pusher block 420.

Support block 440 may be disposed on proximal end region 340a of support member 340. As described above, support block 440 may include a pair of legs 444a-b extending from 25 the distal end of the support block 440, each of legs 444a-b having an inward directed tab 445a-b adapted to engage grooves 413a-b formed on the surface of carrier block 410 to selectively couple support block 440 to carrier block 410.

Carrier block 410, pusher block 420, cover block 430, and support block 440 are shown in Figs. 2, 3A, 4-5 in their fully coupled state, with support block 440 coupled to carrier 30 block 410, pusher block 420 coupled to carrier block 410, and cover block 430 coupled to pusher block 420. In this arrangement, carrier assembly 120 comprises a coaxial set of tubes as shown in Fig. 8, with support member 340 slidably retained substantially within carrier member 310, which is in turn slidably retained substantially within pusher member 320, which is in turn slidably retained substantially within cover member 330.

Triggering system 400 of apparatus 100 may include an energy storing element that is used in the final stage of closure element 500 delivery processes. The energy storing element, such as, but not limited to, a spring, such as pusher spring 425 shown in Figs. 1A, 1B, 6 and 7, may be substantially retained in a spring cavity 417 formed in carrier block 410 and coaxially surrounds a proximal end region 310a of carrier member 310. 5 Pusher spring 425 is capable of expanding and contracting, storing potential energy as it is contracted and releasing energy as it expands. In its fully expanded state, the pusher spring 425 has a length that is greater than the length of spring cavity 417. The cross-sectional dimension of pusher spring 425 may be such that it backs up against and 10 contacts the proximal end of pusher block 420. Thus, when pusher spring 425 is in place between carrier block 410 and pusher block 420, pusher spring 425 is capable of imparting a force biasing carrier block 410 away from pusher block 420.

Prior to delivery of closure element 500, the distal end of carrier block 410 is in physical contact with the proximal end of pusher block 420. In this pre-delivery condition, pusher 15 spring 425 is in a contracted state and is maintained fully within spring cavity 417. A catch member 418 serves the function of maintaining the carrier block 410 and pusher block 420 in the pre-delivery condition against the spring force of pusher spring 425, the force of which would otherwise force apart carrier block 410 from pusher block 420. Catch member 418 may be a U-shaped piece of metal, plastic, or other rigid material that 20 engages first groove 419a formed on the surface of carrier block 410 and second groove 419b formed on the surface of pusher block 420. With reference to Figs. 1A and 1B, pusher block 420 includes hole 426 extending through a portion thereof, with one end of hole 426 opening into groove 419b. Hole 426 is adapted to receive trip pin 427. During 25 the closure element deployment process, trip pin 427 is advanced through hole 426, where it encounters catch member 418 retained in the groove 419b. Further advancement of trip pin 427 causes catch member 418 to become disengaged from groove 419b, thereby releasing the force of pusher spring 425.

The operation of the triggering system 400 of the apparatus 100 is illustrated in Figs. 2-8 with the closure element 500 disposed substantially within the apparatus 100. As shown 30 in Figs. 2-3B, apparatus 100 has an initial position in which locator assembly block 280 is extended proximally and triggering system 400 is in its most proximal position. Accordingly, the locator assembly 200 is in its unexpanded state, as shown in Fig. 3B. At a point in time that the distal end region 210b of the locator assembly 200 has been positioned as desired (for example, within the blood vessel), locator assembly block 280

is depressed distally, as shown in Fig. 4, thereby transitioning locator assembly 200 to the expanded state, as shown in Fig. 3C, and, simultaneously, releasing triggering system 400 from the initial position (in the manner described above) such that triggering system 400 can be advanced distally within the housing 380.

5 Triggering system 400 can then be advanced distally within housing 380, thereby advancing tube set 305 into position adjacent the blood vessel. At a first predetermined position, shown in Figs. 4 and 5, support block 440 encounters a support stop (not shown) on the interior surface of housing bottom half 380d that inhibits support block 440 from advancing further distally. As a result, an application of additional distal force to 10 triggering system 400 causes support block 440 to decouple from carrier block 410. More specifically, tabs 445a-b on legs 444a-b of support block 440 disengage from grooves 413a-b on carrier block 410. Thus, support block 440 remains in the position shown in Fig. 4 and 5, while carrier block 410 is able to advance further distally upon application of force to triggering system 400.

15 Turning to Figs. 6-8, as the triggering system 400 is advanced further distally; cover block 430 engages a cover stop on the interior surface near the distal end region 380b of housing 380, thereby inhibiting additional distal advancement of cover block 430. In addition, trigger extension 405 engages handle 391 of the apparatus, thereby inhibiting additional distal advancement of carrier block 410.

20 Closure element 500 is next deployed by releasing pusher spring 425, which causes pusher block 420 (and, thus, pusher member 320 (Fig. 1A)) to advance distally, deploying closure element 500 in the manner described above. As previously described, pusher spring 425 is released by disengaging catch member 418 from groove 419b on pusher block 420, thereby releasing pusher spring 425 to force pusher block 420 and, thus, 25 pusher member 320 distally relative to carrier block 410. This action causes pusher member 320 to deploy closure element 500 from within tubeset 305. The catch member 418 is disengaged from groove 419b by applying a force to a trigger 401, which, in the deployment position, is aligned with trip pin 427 retained in pusher block 420. A trigger spring 402 biases trigger 401 outward relative to housing 380, with a portion of the 30 trigger 401 extending through a hole 130 (Fig. 1B) in housing 380. A user applies an inward directed force to trigger 401 to counteract the biasing force of trigger spring 402 and force trigger 401 against the trip pin 427.

With reference to Fig. 1A and 6, in addition to deploying closure element 500, the distal advancement of pusher block 420 also causes locator release system 490 to activate,

19 thereby transitioning locator assembly 200 from the expanded state to the unexpanded state. As pusher block 420 advances distally to deploy closure element 500 in the manner described above, pusher block 420 also engages engagement member 493 of locator release system 490 and advances locator release rod 491 distally. This action causes 5 release tab spacer block 492 to disengage from release tabs 284a-b on locator assembly block 280 (see Fig. 1), thereby releasing locator assembly block 280, which returns to its proximal position, causing locator assembly 200 to return to the unexpanded state. An indicator window (not shown) may be formed in housing 380 to give a visual indication that tab spacer block 492 has disengaged and that locator assembly 200 has returned to 10 the unexpanded state. The deployment of closure element 500 and locator release actions occur nearly simultaneously.

Referring now to Figs. 9-13, an alternative embodiment of the apparatus is shown in accordance with the present invention. The apparatus of the alternative embodiment is functionally similar to that of the device previously described above and shown in Figs. 15 1-8 in most respects, wherein certain features will not be described in relation to the alternative embodiment wherein those components function in the manner as described above and are hereby incorporated into the alternative embodiment described below.

Generally, the apparatus 1000 illustrated in Figs. 9-13 can accommodate for variations in the size of the physician's hand and grip by selectively reducing the distance between the 20 device's handle portion and a portion of the triggering system usable to deploy the closure element and/or move a carrier assembly. Advancement of a locator assembly for locating the blood vessel wall prior to deploying the closure element can at least partially advance a portion of the triggering system of the apparatus including a trigger extension graspable by a physician or clinician. This partial movement reduces the gap or throw between the 25 trigger extension and the handle portion. In this manner, a physician or clinician does not need to stretch uncomfortably to position a thumb or finger on the trigger extension, grasping the handle portion, and maintaining the device in the desired orientation relative to the tissue and/or the puncture site.

As shown in Fig. 9, the apparatus 1000 can include a housing 1380 comprising housing 30 halves 1380c and 1380d (Fig. 10). These housing halves 1380c and 1380d (Fig. 10), either individually or collectively, can form one or more handle, hand grip, or finger portions which a physician or clinician can grip or hold to manipulate the apparatus 1000. As illustrated, the apparatus 1000 can include finger grip 1391 and finger grip 1392 at a

distal end and finger grips 1394a and 1394b on the proximal end of housing 1380 to facilitate use of locator assembly 1110, and specifically plunger 1280.

In addition, the apparatus 1000 can include handle, hand grip, or finger portion disposed on the distal end of housing 1380 configured to be engaged by a user when advancing

5 housing 1380 to deploy closure element 500 (Fig. 1A). This handle or handle portion or hand grip portion can include a shaped grasping portion 1600 and an elongate grasping portion 1392 spaced apart from the shaped grasping portion 1600. Each of the portions 1392 and 1600 may be contoured to be received by a user's hand. For instance, the grasping portion 1600 can provide a stable base upon which the physician or clinician can 10 move the device or apparatus as the closure element is positioned and deployed. This grasping portion 1600 can have a shaped portion 1602 having a curved configuration that can receive at least a thumb or finger of the physician as the physician or clinician holds the apparatus 1000. The curved configuration or profile allows the physician to grasp the handle or handle grip portion while resting their hand, wrist or forearm upon a patient 15 during the procedure, such as deployment of the closure element, thereby providing stability during use of the device.

It will be understood that although reference is made to one particular configuration of the handle, hand grip, or finger portions, one skilled in the art will appreciate and can identify various other configurations of handle portion that can perform the function of providing

20 a stable base for manipulation of the apparatus 1000. For instance, and not by way of limitation, the handle portion can be planar rather than curved. Further, the handle portion can include one or more finger receiving holes. In addition, the handle portion can include a material to provide cushioning or comfort to the physician and/or clinician. For example, flexible, yielding, or elastic materials can be formed or applied to all or a 25 portion of the handle portion.

Referring now to Figs. 9 and 10, apparatus 1000 can be provided as one or more integrated components and/or discrete components. For instance, and not by way of limitation, apparatus 1000 may include locator assembly 1110 and carrier assembly 1120.

For purposes of illustration, locator assembly 1110 and carrier assembly 1120 are shown 30 in Fig. 10 as comprising substantially separate assemblies. As desired, however, locator assembly 1110 and carrier assembly 1120 may each be provided, in whole or in part, as one or more integrated assemblies. Portions of locator assembly 110 and/or carrier assembly 120 can also be used as part of apparatus 1000. Alternatively, modified versions of locator assembly 110 and/or carrier assembly 120 can be used.

21 Locator assembly 1110 may be constructed in the manner previously described above, including a flexible or semi-rigid tubular body (such as an elongate rail) with a longitudinal axis. The tubular body can have a proximal end region and a distal end region and can include a predetermined length and a predetermined outer cross-section, 5 both of which can be of any suitable dimension. The distal end region of the locator assembly may include a substantially rounded, soft, and/or flexible distal end or tip to facilitate atraumatic advancement and/or retraction of the distal end region into a blood vessel or other opening in tissue. As desired, a pigtail (not shown) may be provided on the distal end to further aid atraumatic advancement of the distal end region. The distal 10 end region of locator assembly 1110 may be selectively controllable between an unexpanded state and an expanded state.

As shown in Fig. 10, apparatus 1000 can include carrier assembly 1120 which is functionally equivalent to carrier assembly 120 (Fig. 1A) described above and will not be described in detail with regard to the alternative embodiment. As with carrier assembly 15 120, carrier assembly 1120 may be coupled with, and slideable relative to, locator assembly 1110. Carrier assembly 1120 may be configured to receive and retain the closure element 500 (shown in Figs. 14A-14G), which can be disposed substantially within carrier assembly 1120. Carrier assembly 1120 can function to position closure element 500 substantially adjacent to an opening to be closed, and to deploy closure 20 element 500.

Referring now to Figs. 10 and 11, locator assembly 1110 of the alternative embodiment will be described in greater detail. As with the previous locator assembly, a control member 1250, such as a rod, wire, or other elongate member, can be moveably disposed within a lumen (not shown) formed by tubular body 1210 and extend substantially 25 between the proximal end region and the distal end region. Control member 1250 can have a proximal end region 1250a that may be coupled with a control block 1260, and a distal end region that may be coupled with the distal end region of locator assembly 1110, expansion members 1230, and/or movable end regions of substantially flexible members, such as flexible members 232 (Fig. 3B). Control block 1260 may be constructed in a 30 tubular shape and formed of a metal or rigid plastic, and is adapted to be retained in control block cavity 1265 (Fig. 11A) formed on the internal surface of the housing bottom half 1380d, to thereby maintain control block 1260 in a substantially fixed position relative to housing half 1380d and so housing 1380. The locator assembly 1110 can selectively transition distal end region 1210b, expansion members 1230, and/or the

substantially flexible members between the ²² unexpanded and expanded states by moving tubular body 1210 axially relative to control member 1250. Additionally as shown in Fig. 11A, apertures 1383 may be placed adjacent to an in communication with detents 1385, wherein in use as described below, tabs 415a and 415b (Fig. 1A) engage the detents 1385 during use. Apertures 1383 are configured to receive the tip of a medical device, such as a tip of a dilator from a sheath assembly, wherein the tip of the dilator can be utilized to disengage the tabs 415a and 415b (Fig. 1A) from the detents 1385 thereby releasing the locked position of the device. This enables a user to move the trigger assembly 1400 (Fig. 10) proximally (toward the user) after the clip has been deployed in the event that the device becomes stuck within the patient, thereby providing a safety release mechanism. It shall be appreciated that the apertures 1383 may be replaced by other features such a recessed buttons that become exposed with the engagement of the tabs with the detents or alternatively a specific tool may be provided with the device.

With reference to Figs. 10 and 11B, to facilitate movement of carrier assembly 1120 to reduce the distance between a trigger extension 1405 and the distal end of housing 1380, the functionality of locator assembly block 280 (Fig. 1A) can be provided through the combination of a plunger 1280, a tubular body block 1270, and a spring retainer 1290. In addition to providing the functionality of locator assembly block 280, including but not limited to, controlling movement of expansion members 1230, plunger 1280, tubular body block 1270, and spring retainer 1290 aid with moving trigger extension 1405 toward the distal end of housing 1380.

With reference to Fig. 11B, plunger 1280 can include two spaced apart legs 1282a-b separated by a plunger member 1284 to form a slot 1281 therebetween. The legs 1282a-b are spaced apart sufficiently to accommodate or receive a portion of tubular body block 1270 and/or spring retainer 1290 therebetween. Each of the legs 1282a-b can have a stepped configuration, such as shown in Fig. 11D. Plunger 1280 may be slidably received and retained within grooves formed in the proximal end of housing 1380, with the proximal end of plunger 1280 extending from the proximal end of housing 1380.

Plunger 1280 may be constructed of metal, plastic, or other rigid material. The proximal end of plunger 1280 may have a slot 1281 formed therein. Slot 1281 may have a size sufficient to accommodate control block 1260 and control block cavity 1265, and to allow plunger 1280 to travel axially relative to housing 1380. As mentioned, the distal end of plunger 1280 has a pair of distally extending legs 1282a-b with optional ramps 1283a-b on respective inward facing surfaces. In addition, formed in each leg 1282a-b is a recess

1285 within which moves a protrusion 1286 having a dent 1288 that can interlock with at least one of tubular body block 1270 or spring retainer 1290 as plunger 1280 is moved distally.

With reference to Figs. 11B and 11E, tubular body block 1270 may be formed integrally with or attached securely to tubular body 1210. The tubular body block 1270 can include a pair of extending legs 1272a-b, with each of legs 1272a-b having a ramp portion 1273a-b on its inward facing surface. Ramp portions 1273a-b can cooperatively engage tabs, not shown but similar to tabs 415a-b (Fig. 1A), of carrier block 1410 (Fig. 12). In an initial state, the tabs 415a-b (Fig. 1A) can be engaged in slots 1387a-1387b (Fig. 11A) formed in housing halve 1380d to hold triggering system 1400 (Fig. 10) in a fixed axial relationship with housing 1380.

Extending between legs 1272a-b is an intermediate member 1274 that can include a pair of upwardly extending extension 1276a-b and a tab 1278, shown in dotted lines in Fig. 11B. Extensions 1276a-b are received within the space between legs 1282a-b of plunger 1280. Stated another way, tubular body block 1270 can be held in a fixed axial relationship with respect to plunger 1280 through the engagement of legs 1282a-b and legs 1272a-b. The tab 1278 can be adapted to cooperate with spring retainer 1290 and optionally lock with a portion of spring retainer 1290 as plunger 1280 moves distally, as will be described in more detail hereinafter.

Extending from intermediate member 1274 in the same direction as legs 1272a-b is a tubular portion 1279 that slidably cooperates with spring retainer 1290 and receives tubular body 1210 within a lumen. Further, tubular portion 1279 can cooperate with a locator assembly spring 1289 (Fig. 10) which biases tubular body block 1270 and/or spring retainer 1290 relative to housing 1380.

As shown in Figs. 11B and 11F, spring retainer 1290 has a wall portion 1291 with a recess 1292 that can receive tubular portion 1279 of tubular body block 1270. The wall portion 1291 defines a channel 1294 within which can be received locator assembly spring 1289 (Fig. 10). For instance, locator assembly spring 1289 (Fig. 10) can extend from wall portion 1291 to locator assembly spring stop 1381 (Fig. 11A) to bias movement of spring retainer 1290, tubular body block 1270, and so locator assembly 1110.

Spring retainer 1290 can further include arms 1296a-b. Arms 1296a-b can include a movable portion 1297a-b that can flex or move to receive tab 1278 of tubular body block 1270. For instance, tab 1278 can include curved surfaces that cooperate and receive a portion of movable portion 1297a-b as tubular body block 1270 moves relative to spring

retainer 1290. Alternatively, tab 1278 can be positioned within a space 1299 between wall portion 1291 and movable portion 1297a-b before manipulation or operation of apparatus 1000. It will be understood that other portions of arms 1296a-b can flex or move, whether or not movable portions 1297a-b move.

5 In addition to arms 1296a-b, spring retainer 1290 can include release tabs 1298a-b. These release tabs 1298a-b can function in a similar manner to tabs 284a-b (Fig. 1A). For instance, tabs 1298a-b can cooperate with a locator release system 1490 in a manner substantially similar to the embodiments described above. For example, release tabs 1298a-b can engage release cavity 1495 on housing 1380, and can be held from releasing 10 by release tab spacer block 1492.

Generally, plunger 1280, tubular body block 1270, and spring retainer 1290 can be formed of metal, plastic, or other material, whether or not rigid, substantially rigid, or flexible. As such, plunger 1280, tubular body block 1270, and spring retainer 1290 can be formed from medical grade synthetic materials or materials that can be sterilized or 15 otherwise cleaned.

Turning now to Figs. 12 and 13, illustrated are the operational positions of the apparatus 1000 in (i) an initial state with the expansion members 1230 (Fig. 9) in an unexpanded condition and (ii) a state with the expansion members 1230 (Fig. 9) in an expanded condition.

20 With reference to Fig. 12, in the initial state plunger 1280 extends from the distal end of housing 1380, expansion members 1230 are in an unexpanded condition, and locator assembly spring 1289, which can be located coaxially with tubular body block 1270, may be located between spring retainer 1290 and the proximal side of locator assembly spring stop 1381 formed on the inner surface of housing bottom half 1380d. In this initial state 25 locator assembly spring 1289 is held in a biased state. Optionally, a portion of carrier assembly 1120 (Fig. 10) can be associated with legs 1282a-b of plunger 1280 and contact carrier a portion of carrier assembly 1120 (Fig. 10).

Once a user presses on plunger 1280 to expand expansion members 1230, that is moving plunger 1280 toward expansion members 1230, tubular body block 1270 and tubular body 1210 are advanced distally by distal advancement of plunger 1280. Upon advancement, and with reference to Fig. 1A and 10-12, ramp members 1273a-b press tabs 415a-b, which are hidden by plunger 1280 in Fig. 12, releasing carrier block 1410 to slide axially in housing 1380, and release tabs 1298a-b engage in retaining grooves 1387a-b in cooperation with locator release system 1490, which is functionally equivalent to locator

release system 490 described above, thereby fixing spring retainer 1290 and tubular body block 1270 axially with respect to housing 1380, and fixing expansion members 1230 of locator assembly 1110 in an expanded state. Also during advancement, tab 1278 of tubular body block 1270 advances between arms 1296a-b of spring retainer 1290, 5 extending the arms outwardly until tab 1278 advances past the ends of arms 1296a-b, causing arms 1296a-b to extend behind tab 1278, thereby coupling spring retainer 1290 and tubular body block 1270, and fixing tubular body block axially prior to activation of locator release system 1490. Also, once advanced the plunger 1280 is locked into a distal position by legs 1272a and 1272b.

10 Further axial movement of plunger 1280 can allow engagement of distal end 1283b of leg 1282b and carrier block 1410, thereby moving carrier block 1410 distally along with carrier assembly 1120, as illustrated in Fig. 13. This additional movement of carrier assembly 1120 also moves trigger extension 1405, shortening the distance required to fully engage the carrier assembly 1120. Combining the deployment of locator assembly 15 1110 and the partial advancement of carrier assembly 1120 in a single step, allows for a reduction in travel of the trigger block and trigger extension 1405. This reduction of travel allows for a greater variation in user strength as well as the physical size of a users hand to fit better with device 1000 as illustrated.

Once locator assembly 1110 is deployed, carrier assembly 1120 can be advanced distally 20 by exerting force on trigger extension 1405, and can be fixed in the distal position in the manner described above with reference to other embodiments above. After the locator has been deployed and the carrier assembly initially advanced as shown in Fig. 13, device 1000 functions in the manner described above with regard to other embodiments of the present invention and thus will not be described in detail with regard to this embodiment.

25

In some embodiments, the tubular body block and the release block may be integrally formed. When the tubular body block and the release block are integrally formed, axial movement of the locator assembly block can force outward movement of tabs holding the tubular body block to the locator assembly block, allowing the integrally formed tubular 30 body block and release block to slide distally with respect to the locator assembly block, and cause the release tabs to load the locator release system to release as discussed above. Referring now to Figs. 14A-14G illustrating embodiments of a closure element that can be used as part of or with the apparatus 100. The closure element, generally identified with reference numeral 500, may have a generally annular-shaped body defining a

26

channel and one or more barbs and/or tines for receiving and engaging the blood vessel wall and/or the tissue around the opening. Although the closure element has a natural shape and size, the closure element can be deformed into other shapes and sizes, as desired, and can be configured to return to the natural shape and size when released. For 5 example, closure element 500 can have a natural, planar configuration with opposing tines and a natural cross-section. The closure element can be formed from any suitable material, including any biodegradable material, any shape memory material, such as alloys of nickel-titanium, or any combination thereof. Additionally, it is contemplated that the closure element may be coated with a beneficial agent or be constructed as a 10 composite, wherein one component of the composite would be a beneficial agent. As desired, the closure element may further include radiopaque markers (not shown) or may be wholly or partially formed from a radiopaque material to facilitate observation of the closure element using fluoroscopy or other imaging systems. Exemplary embodiments of a closure element are disclosed in U.S. Patents Nos. 6,197,042, 6,623,510, 6,461,364, 15 6,391,048, and 6,623,510. The disclosures of these references and any others cited therein are expressly incorporated herein by reference.

As described previously, and with reference to Fig. 15A, closure element 500 can be disposed within the carrier assembly and adjacent to the distal end of pusher tube 320. As shown in Fig. 15A, for example, the reduced closure element 500 may be slidably 20 received over distally-increasing cross-section 318b of distal end region 310b of carrier member 310 and disposed about periphery 312 of carrier member 310 adjacent to space 360. Since reduced cross-section 530 of reduced closure element 500 is less than cross-section 318b of distally-increasing cross-section 318b, reduced closure element 500 must be temporarily radially deformed to be received over distal end region 310b. Also, as 25 reduced closure element 500' (Fig. 14C) is received over distal end region 310b, opposing tines 520 of reduced closure element 500' (Fig. 14C) engage distal end region 310b. Reduced closure element 500' (Fig. 14C) thereby forms substantially tubular closure element 500", illustrated in Fig. 14G, with the ends of the barbs and/or tines extending towards the distal end of the apparatus 100.

30 The apparatuses of the present invention may be configured to be utilized with a sheath, wherein the sheath is inserted or otherwise positioned into an opening in a body comprising a lumen. The sheath generally comprises a substantially flexible or semi-rigid tubular member having a proximal end region and a distal end region and includes a predetermined length and a predetermined cross-section, both of which can be of any

suitable dimension. The sheath forms a lumen that extends along a longitudinal axis or the sheath and substantially between the proximal and distal end regions. The lumen can have any suitable internal cross-section and is suitable for receiving one or more devices (not shown), such as a catheter, a guide wire, or the like. The lumen is configured to 5 slidably receive the tubular body of the locator assembly and/or the tube set of the carrier assembly of the devices in accordance with the present invention.

Since the internal cross-section of the sheath may be less than or substantially equal to the predetermined cross-section of the cover member, the sheath may be configured to radially expand, such as by stretching, to receive the tube set. Alternatively, or in 10 addition, the sheath may be advantageously configured to split as the tube set is received by, and advances within the lumen of the sheath, thereby permitting the apparatuses to access the blood vessel wall. To facilitate the splitting, the sheath can include one or 15 more splits, such as longitudinal splits, each split being provided in a manner known in the art. Each split is configured to split the sheath in accordance with a predetermined pattern, such as in a spiral pattern. It will be appreciated that, when the internal cross-section of the sheath is greater than the predetermined cross-section of the cover member, it may not be necessary for the sheath to be configured to radially expand and/or split. In addition to, or as an alternative to, the apparatus may include a cutting means that initiates 20 a tear line or split in the sheath when the sheath is engaged with the distal end of the apparatus.

The sheath may be advanced over a guide wire or other rail (not shown), which has been positioned through the opening and into the blood vessel using conventional procedures such as those described above. Preferably, the blood vessel is a peripheral blood vessel, such as a femoral or carotid artery, although other body lumens may be accessed using 25 the sheath as will be appreciated by those skilled in the art. The opening, and consequently the sheath, may be oriented with respect to the blood vessel such as to facilitate the introduction of devices through the lumen of the sheath and into the blood vessel with minimal risk of damage to the blood vessel. One or more devices (not shown), such as a catheter, a guide wire, or the like, may be inserted through the sheath 30 and advanced to a preselected location within the patients body. For example, the devices may be used to perform a therapeutic or diagnostic procedure, such as angioplasty, atherectomy, stent implantation, and the like, within the patients vasculature.

Figs. 15A-K illustrate one exemplary manner to deploy closure element 500 by apparatuses according to the present invention. For purposes of continuity, reference

numbers to the first discussed embodiment are used, but it will be evident that other embodiments discussed above may be used in a similar fashion.

A sheath 640 may be inserted or otherwise positioned through a patient's skin 650 and tissue 630 and within the blood vessel 600 or other body lumen via the opening 610. This 5 provides access to the blood vessel 600 through the blood vessel wall 620 for performance of a therapeutic or diagnostic procedure.

After the procedure is completed, the devices associated with the therapeutic or diagnostic procedure are removed from sheath 640, and apparatus 100 can be prepared to be received by lumen 644 of the sheath. Being in the unexpanded state, the distal end 10 region 210b of tubular body 210 of the locator assembly 200 can be slidably received by the lumen and atraumatically advanced distally into the blood vessel 600, as illustrated in Figs. 15B. Once the distal end region 210b extends into blood vessel 600, distal end region 210b can transition from the unexpanded state to the expanded state by activating the switching system of locator assembly 200, and as illustrated in Fig. 15C. As 15 discussed with reference to the embodiments described in reference to Figs. 9-13, the carrier assembly may be partially advanced when the locator assembly is transitioned from the unexpanded to the expanded state by pressing the locator assembly block distally with respect to the housing.

Turning to Fig. 15D, apparatus 100 and/or sheath 640 can then be retracted proximally 20 until distal end region 210b is substantially adjacent to an outer surface 620b of blood vessel wall 620. Distal end region 210b thereby draws blood vessel wall 620 taut and maintains the proper position of apparatus 100 as blood vessel 600 pulsates. Since the expanded cross-section of distal end region 210b is greater than or substantially equal to the cross-section of opening 610 and/or the cross-section of lumen 644, distal end region 25 210b remains in blood vessel 600 and engages inner surface 620b of blood vessel wall 620. Distal end region 210b can frictionally engage inner surface 620b of blood vessel wall 620, thereby securing apparatus 100 to blood vessel 600. Sheath 640 can be retracted proximally such that distal end region 640b of sheath 640 is substantially withdrawn from blood vessel 600, permitting apparatus 100 to access blood vessel wall 30 620.

Once distal end region 210b of locator assembly 200 contacts inner surface 620b of blood vessel wall 620, tube set 305 can then be advanced distally and received within lumen 644 of sheath 640. In the manner described above, sheath 640 can radially expand and/or split in accordance with the predetermined pattern as tube set 305 advances because the

internal cross-section of sheath 640 is less²⁹ than or substantially equal to pre-determined cross-section 338b of cover member 330. Being coupled, carrier member 310, pusher member 320, cover member 330, and support member 340 each advance distally and approach the first predetermined position, as illustrated in Fig. 15F. As discussed with reference to the embodiments described in reference to Figs. 9-13, a stable base can be provided by handle portion 1600 having an enlarged, curved configuration that can receive at least a thumb or finger of the physician. The enlarged, curved handle portion 1600 can be gripped by the physician while the physician's hand is rested upon a patient during the procedure and provide stability during use of the device. Additionally, the combined deployment of locator assembly 1110 and the partial advancement of carrier assembly 1120 in a single step allows for a reduction in travel of trigger extension 1405. Thus, a user does not need to reach uncomfortably far from handle portion 1602 to trigger extension 1405 to fully advance carrier assembly 1120 and the tube set coupled to the carrier assembly.

Upon reaching the first predetermined position, tube set 305 is disposed substantially adjacent to outer surface 620a of blood vessel wall 620 adjacent to opening 610 such that the blood vessel wall adjacent to opening 610 is disposed substantially between expanded distal region 210b of locator assembly 200 and tube set 305. Support member 340 decouples from carrier member 310 and pusher member 320 in the manner described above when tube set 305 is in the first predetermined position. The cover member 330 and pusher member 320 are advanced. After advancement the cover member 330 is decoupled from the carrier member 310 and pusher member 320. Thereby, cover member 330 and support member 340 may be inhibited from further axial movement and remain substantially stationary as carrier member 310 and pusher member 320 each remain coupled and axially slid able.

As shown in Fig. 15G, cover member 330 and support member 340 remain substantially stationary while carrier member 310 and pusher member 320 continue distally and approach the second predetermined position. As carrier member 310 and pusher member 320 distally advance toward the second predetermined position, annular cavity 370 moves distally relative to substantially-stationary cover member 330 such that distal end region 330b of cover member 330 no longer encloses annular cavity 370. Thereby, closure element 500 is not completely enclosed by annular cavity 370 formed by distal end regions 310b, 320b, and 330b of carrier member 310, pusher member 320, and cover member 330.

30
Although not completely enclosed by annular cavity 370, substantially tubular closure element 500 is advantageously retained on outer periphery 312b of carrier member 310 by distal end region 330b of cover member 330 as illustrated in Fig. 15G. For example, by retaining substantially tubular closure element 500 between distal end region 330b of 5 cover member 330 and distal end region 310b carrier member 310, apparatus 100 may be configured to provide better tissue penetration. The timing between the deployment of substantially tubular closure element 500 by tube set 305 and the retraction and transition to the unexpanded state by locator assembly 200 likewise is facilitated because substantially tubular closure element 500 is retained between distal end region 330b and 10 distal end region 310b. Further, carrier member 310 and cover member 330 operate to maintain substantially tubular closure element 500 in the tubular configuration.

When tube set 305 is in the second predetermined position, carrier member 310 decouples from pusher member 320 in the manner described in detail above. Therefore, carrier member 310, cover member 330, and support member 340 may be inhibited from further 15 axial movement and remain substantially stationary, whereas, pusher member 320 remains axially slidable. As pusher member 320 continues distally, distal end region 320b of pusher member 320 contacts substantially tubular closure element 500 and displaces substantially tubular closure element 500 from space 360 as shown in Figure 15H. Since space 360 is substantially radially exposed, pusher member 320 directs 20 substantially tubular closure element 500 over the distally-increasing cross-section of distal end region 310b of substantially-stationary carrier member 310 such that the cross-section of substantially tubular closure element 500 begins to radially expand, preferably in a substantially uniform manner. As substantially tubular closure element 500 traverses the distally-increasing cross-section of distal end region 310b, the cross-section of 25 substantially tubular closure element 500 radially expands beyond natural cross-section of closure element 500, as shown in Figs. 14A-G.

Upon being directed over the distally-increasing cross-section of the distal end region by pusher member 320, substantially tubular closure element 500 is distally deployed as 30 illustrated in Fig. 15I. When substantially tubular closure element 500 is deployed, tines 520 can pierce and otherwise engage significant amount of blood vessel wall 620 and/or tissue 630 adjacent to opening 610. For example, tines 520 can engage significant amount of blood vessel wall 620 and/or tissue 630 because cross-section 530 of substantially tubular closure element 500 is expanded beyond natural cross-section 530 of closure element 500 during deployment.

As the closure element is being deployed³¹ from the space, locator assembly 200 may begins to retract proximally and locator release system 490 can be activated to transition from the expanded state to the unexpanded state as substantially tubular closure element 500 is deployed. Distal end region 210b of locator assembly 200 may retract proximally 5 and transition from the expanded state to the unexpanded state substantially simultaneously with the deployment of substantially tubular closure element 500. As desired, distal end region 210b may be configured to draw blood vessel wall 620 and/or tissue 630 adjacent to opening 610 proximally and into the channel defined by substantially tubular closure element 500. Tines 520 of substantially tubular closure element 500 thereby can pierce and otherwise engage blood vessel wall 620 and/or tissue 630.

Turning to Fig. 15J, substantially tubular closure element 500, once deployed, begins to transition from the tubular configuration, returning to the natural, planar configuration with opposing tines 520 and a natural cross-section of closure element 500. Preferably, 15 substantially tubular closure element 500 substantially uniformly transitions from the tubular configuration to the natural, planar configuration. Rotating axially inwardly to from opposing tines 520 of the closure element 500, tines 520 draw the tissue into the channel as substantially tubular closure 500 element forms closure element 500. Also, the tissue is drawn substantially closed and/or sealed as the cross-section of substantially 20 tubular closure element 500 contracts to return to the natural cross-section.

It will be appreciated that the closure element may be constructed of other materials, that it may comprise alternative shapes, and that it may adopt alternative methods of operation such that the closure element achieves closure of openings in blood vessel walls or other body tissue. In an additional non-limiting example, the closure element is constructed of 25 materials that use a magnetic force to couple a pair of securing elements in order to close an opening in the lumen wall or tissue. In this alternative embodiment, the closure element may be of a unitary or multi-component construction having a first securing element positionable at a first position adjacent the opening, and a second securing element positionable at a second position adjacent the opening. The first and second securing elements are provided having a magnetic force biasing the first and second securing elements together, thereby closing the opening, or they are provided having a magnetic force biasing both the first and second securing elements toward a third securing element positioned in a manner to cause closure of the opening. The magnetic closure element may be provided without tines, provided the magnetic force coupling the 30

closure elements is sufficient to close the opening. Alternatively, the closure element may be provided with a combination of the magnetic securing elements and tines to provide a combination of coupling forces. Those skilled in the art will recognize that other and further materials, methods, and combinations may be utilized to construct the closure element to achieve the objectives described and implied herein.

The invention is susceptible to various modifications and alternative means, and specific examples thereof have been shown by way of example in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular devices or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the claims.

³³
CLAIMS

We claim:

1. An apparatus for delivering a closure element to an opening formed in a wall of a body lumen, the apparatus comprising:

5 a locator assembly having a distal end region configured to extend into the opening and selectively contact the wall of the body lumen and a proximal end configured to cooperate with a movable plunger,

10 a carrier assembly coupled with said locating assembly, said carrier assembly retaining the closure element in a substantially tubular configuration within said carrier assembly; and

a triggering system cooperating with said locator assembly, said triggering system moveable toward the distal end region of said locator assembly as said movable plunger moves toward said distal end region.

2. The apparatus as recited in claim 1, further comprising a housing receiving 15 said locator assembly, said carrier assembly, and said triggering system.

3. The apparatus as recited in claim 1, wherein said locator assembly being configured to selectively control said distal end region of said locator assembly between said expanded state and said unexpanded state.

4. The apparatus as recited in claim 3, wherein said locator assembly further 20 comprises a control member coupled to at least one expansion member and a tubular member surround said control member.

5. The apparatus as recited in claim 4, wherein said locator assembly further comprises a tubular body block mounted to said tubular member, a spring retainer receiving a portion of said tubular body block, and said movable plunger slidably 25 cooperating with said tubular body block and said tubular member.

6. The apparatus as recited in claim 1, wherein said distal end region of said locator assembly is configured to transition from an unexpanded state to an expanded state.

30 7. The apparatus as recited in claim 6, wherein said triggering system moves toward said distal end region substantially simultaneously with said distal end region transitioning from said unexpanded state to said expanded state.

8. An apparatus for placement into an opening formed in a wall of a body lumen, the apparatus comprising:

a housing comprising a handle portion formed at a distal end, said handle portion comprising a shaped grasping portion and an elongate grasping portion;

5 a locator assembly receivable by said housing, said locator assembly having a distal end region configured to extend into the opening and selectively contact the wall of the body lumen; and

10 a carrier assembly coupled with said locating assembly, said carrier assembly retaining a closure element in a substantially tubular configuration within said carrier assembly, said closure element being deployable from within a portion of said carrier assembly to close the opening formed in the wall of the body lumen.

9. The apparatus as recited in claim 8, wherein said shaped grasping portion is spaced apart from said elongate grasping portion.

10. The apparatus as recited in claim 8, wherein said distal end of said housing further comprises at least one distal handle portion extending from said housing in a direction substantially opposite to at least one of said grasping portions.

11. The apparatus as recited in claim 8, wherein said shaped grasping portion has a generally curved configuration with a recess adapted to receive at least one of a thumb or finger during use of the apparatus.

12. The apparatus as recited in claim 8, wherein said apparatus further 20 comprises a trigger extension coupled to and extending from said carrier assembly, said trigger extension being configured to advance the carrier assembly prior to deployment of the closure element.

13. The apparatus as recited in claim 12, wherein said trigger extension is 25 movable toward said distal end region of said locator assembly upon activation of a locator control system to at least partially deploy at least one expansion element, disposed at said distal end region, configured to expand substantially transversely with respect to a longitudinal axis of said locator assembly.

14. An apparatus for placement into an opening formed in a wall of a body lumen to deploy a closure element, the apparatus comprising:

30 a housing comprising a handle portion formed at a distal end, said handle portion configured to be engaged by a user when advancing said housing to deploy the closure element;

a locator assembly receivable by said housing, said locator assembly having one or more expansion members configured to expand substantially

35

transversely with respect to a longitudinal axis of said locator assembly to selectively contact the wall of the body lumen and a proximal end configured to cooperate with a portion of a locator control system operable to expand said one or more expansion members;

5 a carrier assembly coupled with said locating assembly, said carrier assembly retaining a closure element in a substantially tubular configuration within said carrier assembly, said closure element being deployable from within a portion of said carrier assembly to close the opening formed in the wall of the body lumen; and

10 a triggering system cooperating with said locator assembly, said triggering system moveable toward said one or more expansion members of said locator assembly upon said locator control system being operated to expand said one or more expansion members.

15. The apparatus as recited in claim 14, wherein said housing further comprises at least one proximal handle portion configured to be engaged by the user when advancing said proximal end of said locating assembly.

16. The apparatus as recited in claim 15, wherein said triggering system further comprises a trigger extension coupled to and extending from said carrier assembly, said trigger extension being configured to advance said carrier assembly prior 20 to deployment of said closure element.

17. The apparatus as recited in claim 14, wherein each of said one or more expansion members comprises one or more substantially flexible members.

18. The apparatus as recited in claim 14, wherein said locator control system is configured to selectively control said distal end region of said locator assembly between 25 said expanded state and said unexpanded state.

19. The apparatus as recited in claim 18, wherein said locator assembly further comprises a control member coupled to said one or more expansion members and a tubular body surrounding said control member, said locator assembly further comprising a tubular body block mounted to said tubular member, a spring retainer receiving a 30 portion of said tubular body block, and a movable plunger slidably cooperating with said tubular body block and said tubular member.

20. The apparatus of claim 14, wherein said carrier assembly comprises a carrier member for receiving and supporting said closure element in said substantially tubular configuration, a pusher member for distally deploying said closure element, and a

36
cover member for retaining said closure element, said carrier member, said pusher member, and said cover member being slidably coupled.

21. The apparatus of claim 20, wherein said carrier member, said pusher member, and said cover member are provided as a plurality of nested, telescoping members with a common longitudinal axis.

22. The apparatus of claim 21, wherein said carrier member defines a lumen, said distal end region of said locator assembly being substantially axially aligned with, and at least partially slidably disposable within, said lumen of said carrier member.

23. The apparatus of claim 22, wherein said distal end region of said carrier member has a cross-section that increases distally for expanding said closure element to a cross-section that is greater than a natural cross-section of said closure element.

24. The apparatus of claim 23, wherein said distal end region of said pusher member includes one or more longitudinal extensions extending distally and being configured to expand radially as said distal end region of said pusher member moves distally and engages said distally-increasing cross-section of said distal end region of said carrier member.

25. The apparatus of claim 24, wherein said distal end region of said cover member includes one or more longitudinal extension extending distally and being configured to expand radially.

26. The apparatus of claim 20, wherein said carrier assembly further includes a support member being slidably coupled with said carrier member, said pusher member, and said cover member and being configured to provide radial support for said distal end region of said cover member.

27. The apparatus of claim 26, wherein said carrier member, said pusher member, said cover member, and said support member are provided as a plurality of nested, telescoping members with a common longitudinal axis.

1 / 26

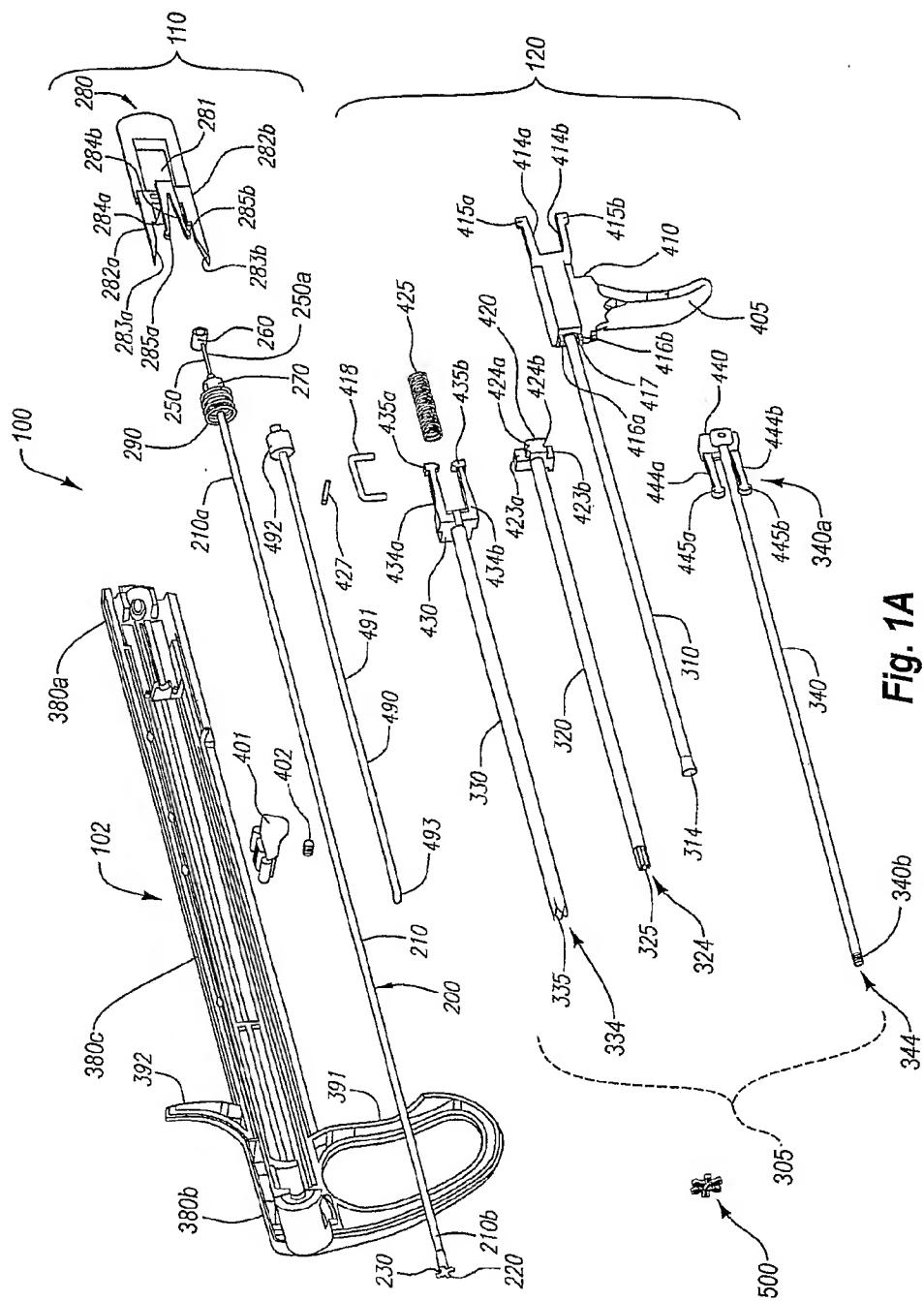


Fig. 1A

2 / 26

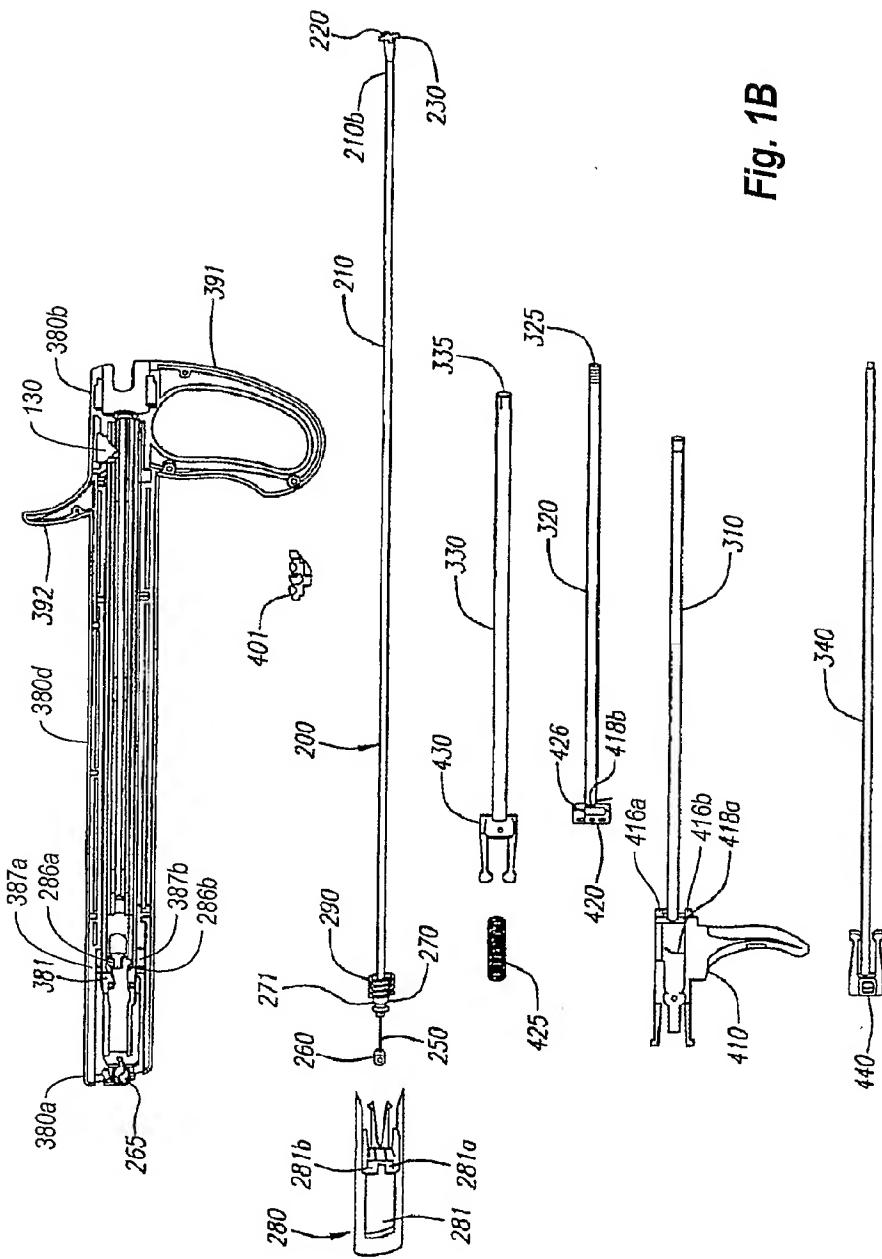


Fig. 1B

3 / 26

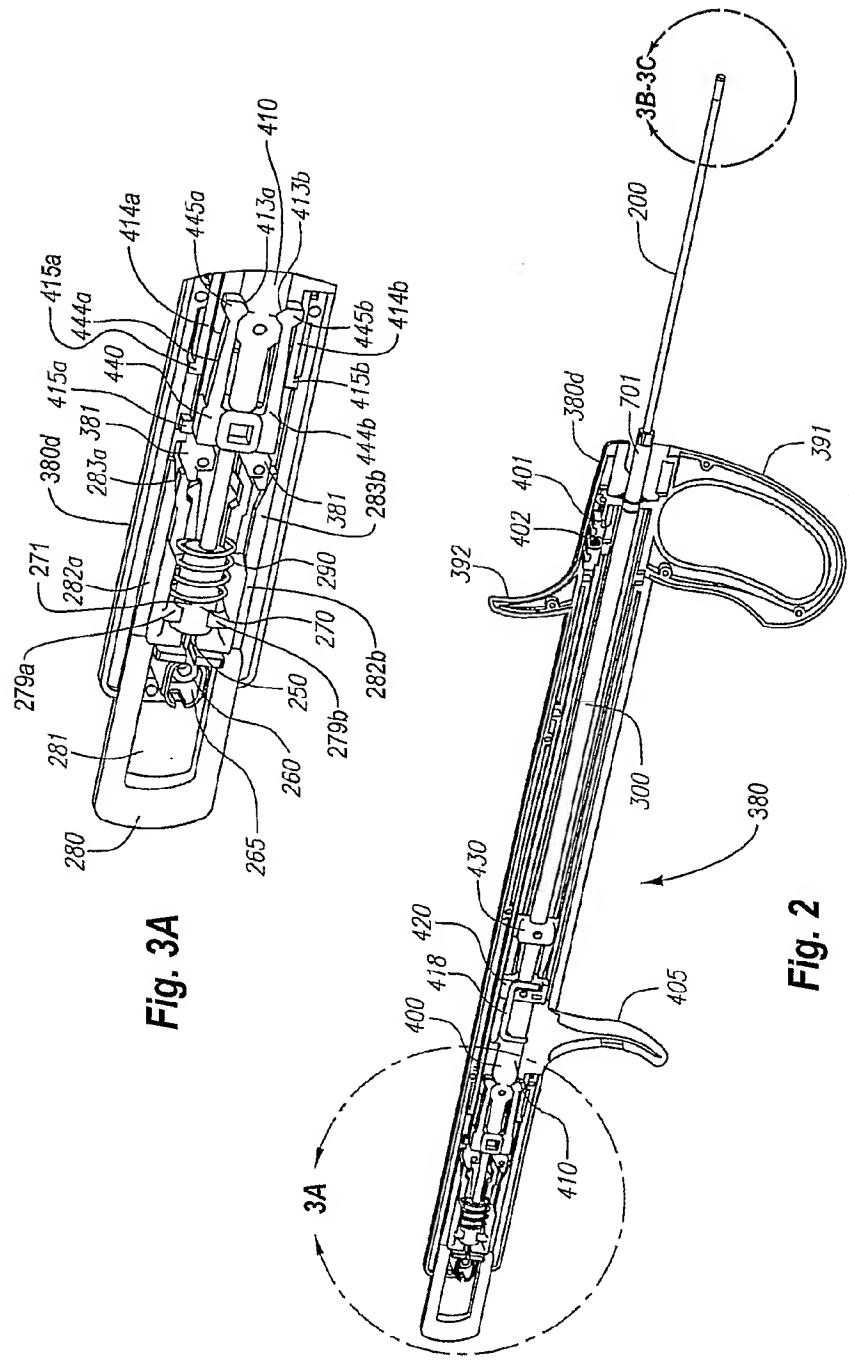
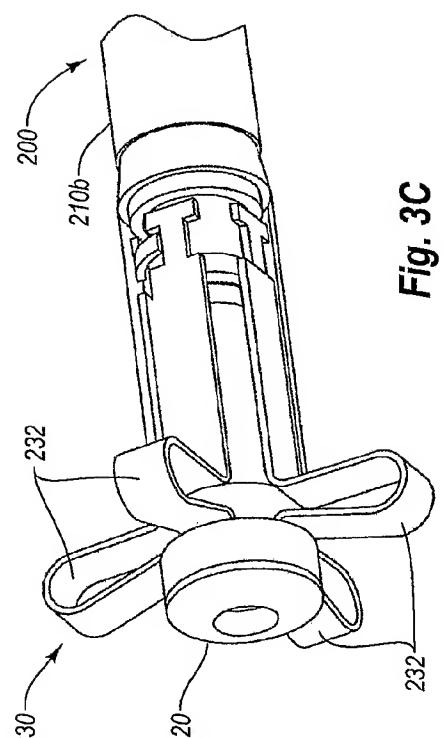
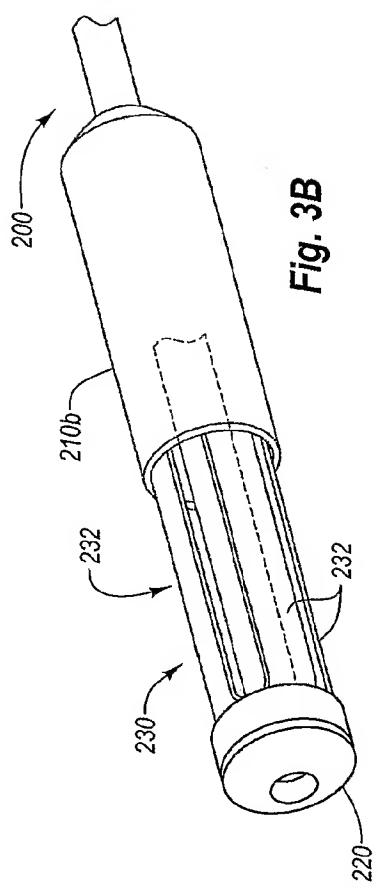


Fig. 3A

4 / 26



5 / 26

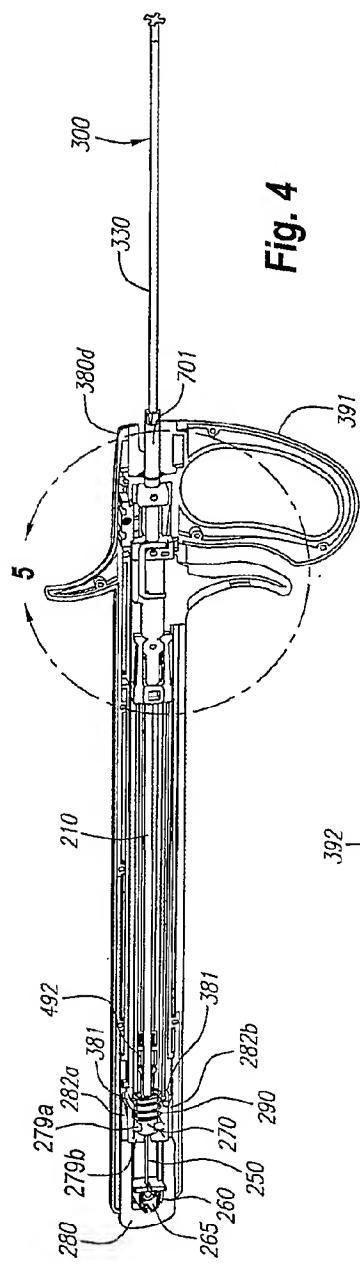


Fig. 4

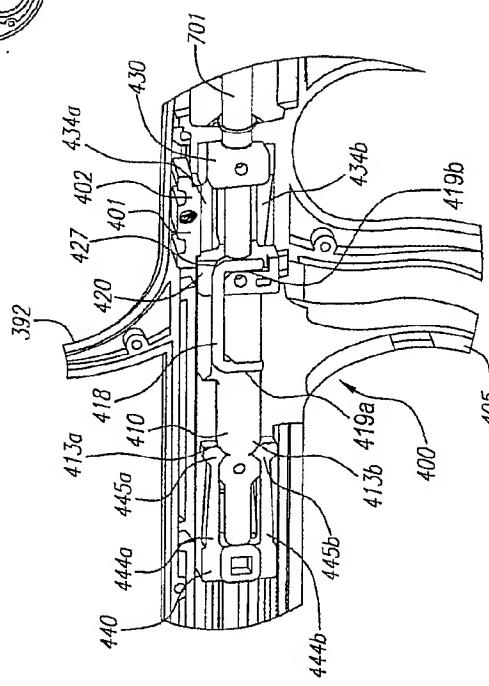
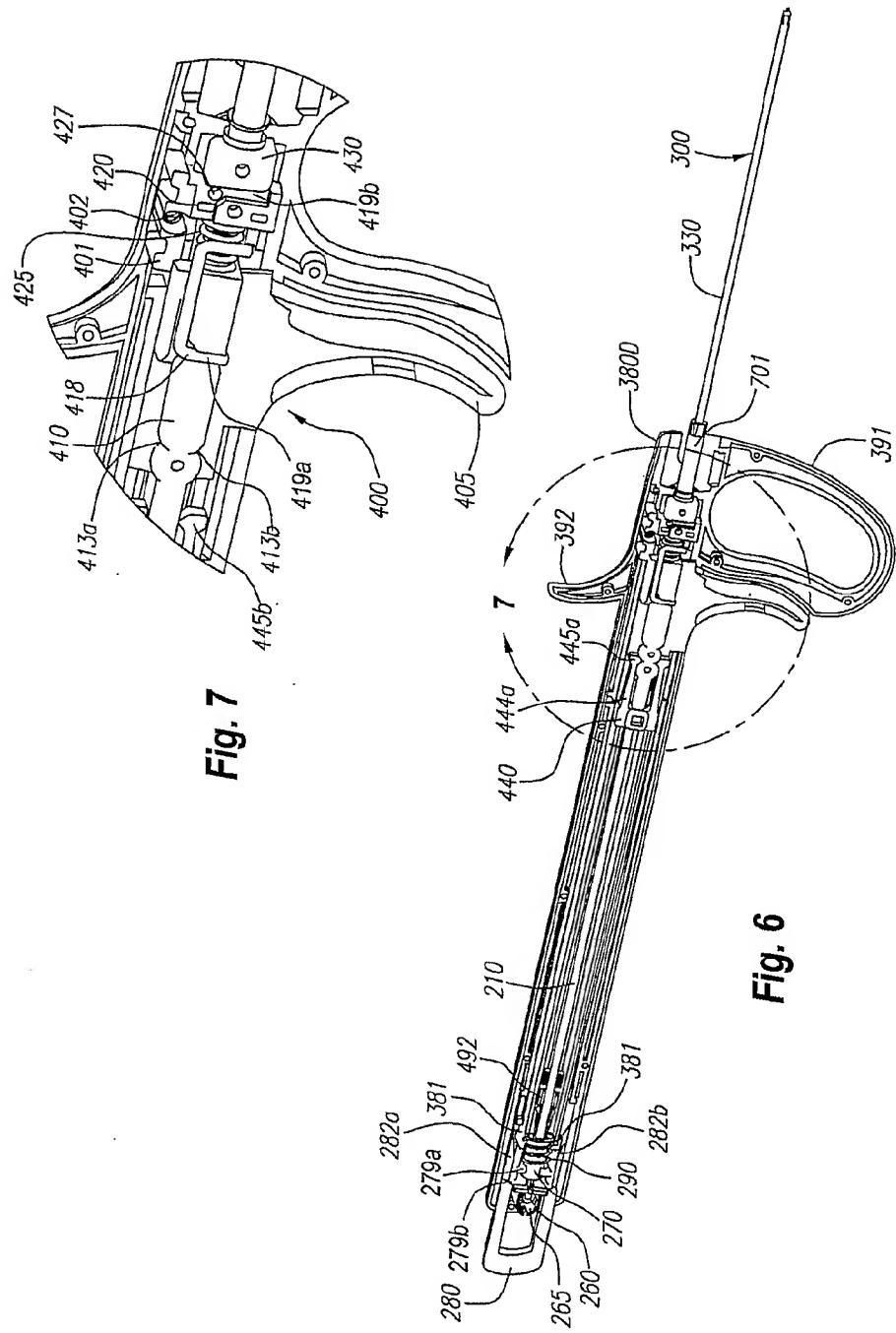


Fig. 5

6 / 26



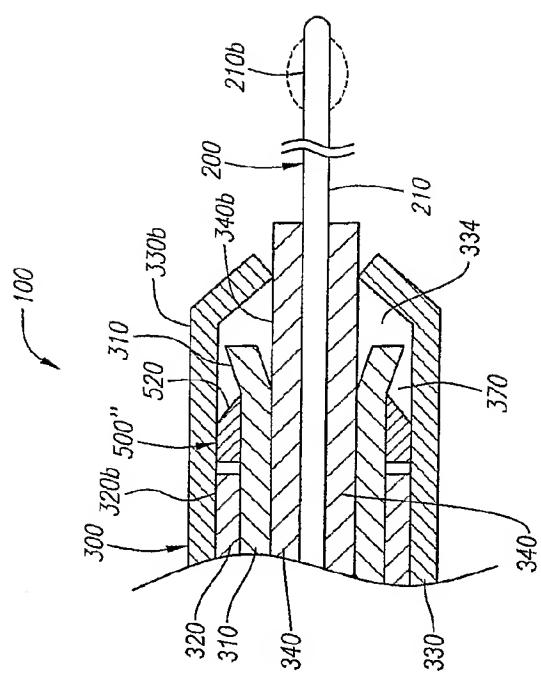


Fig. 8

8 / 26

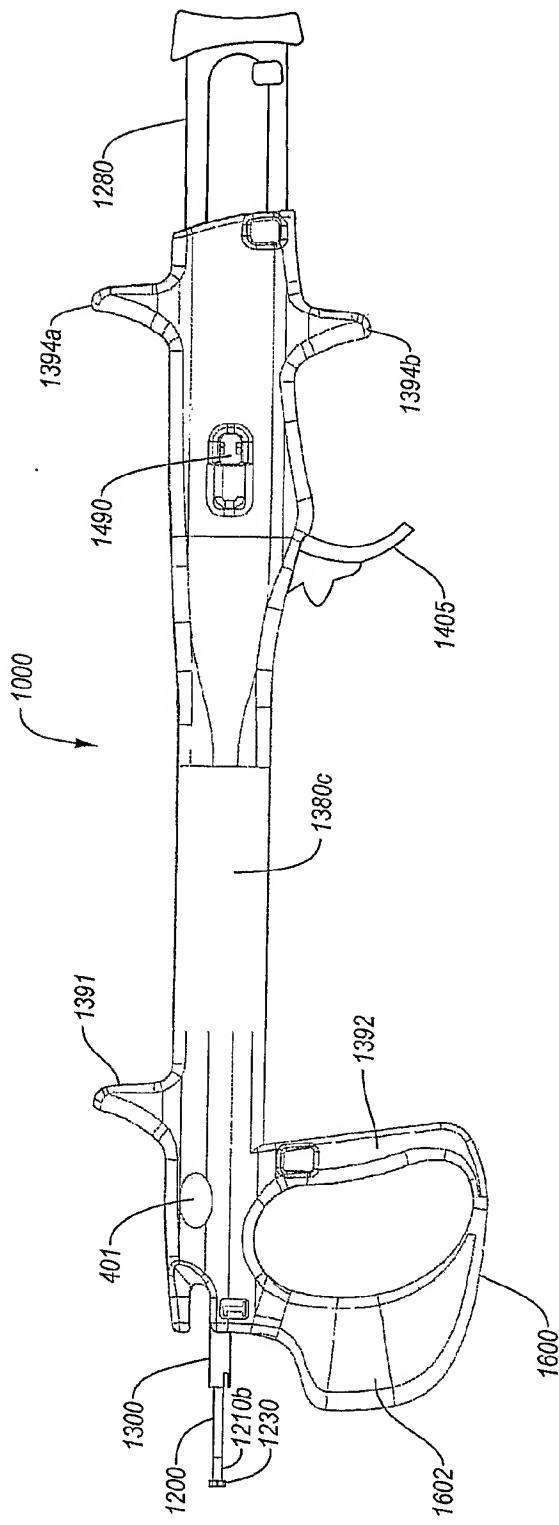


Fig. 9

9 / 26

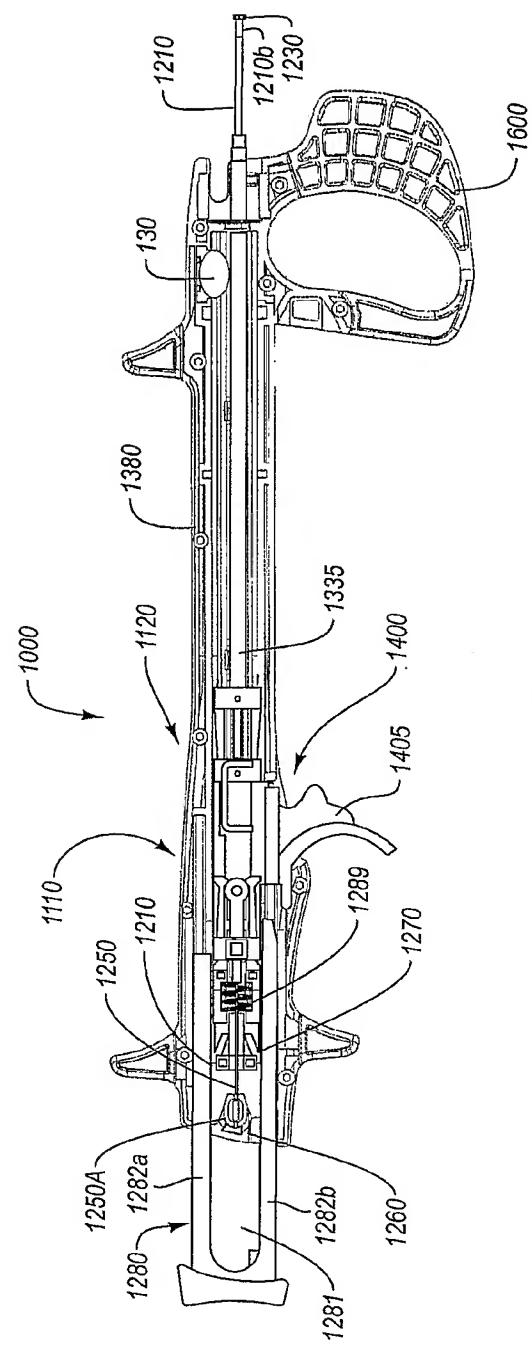


Fig. 10

10 / 26

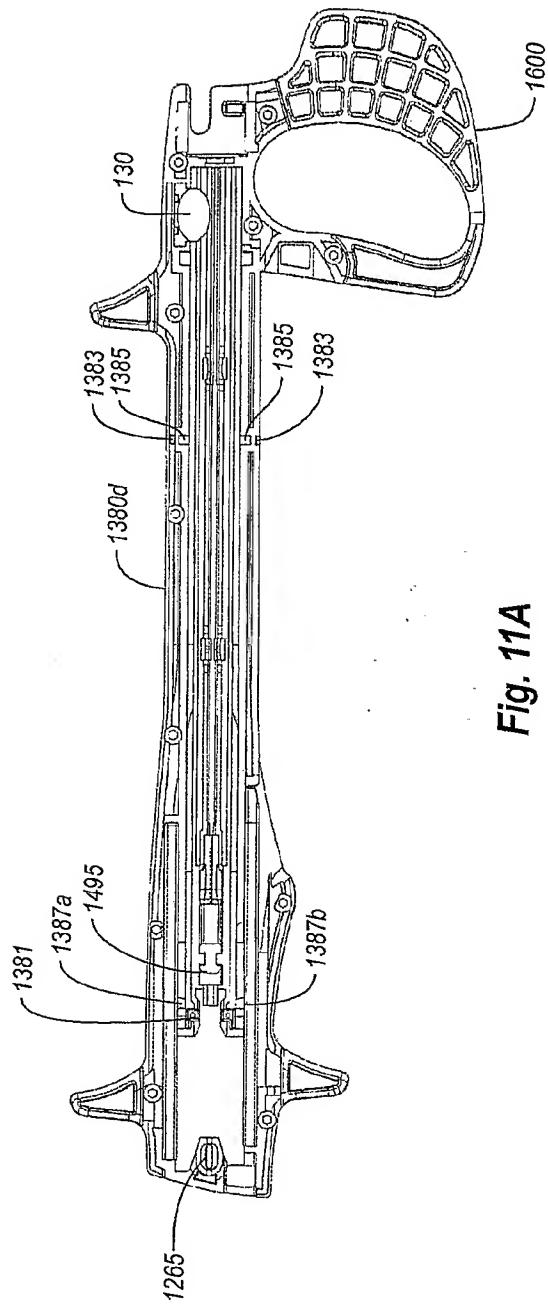


Fig. 11A

11 / 26

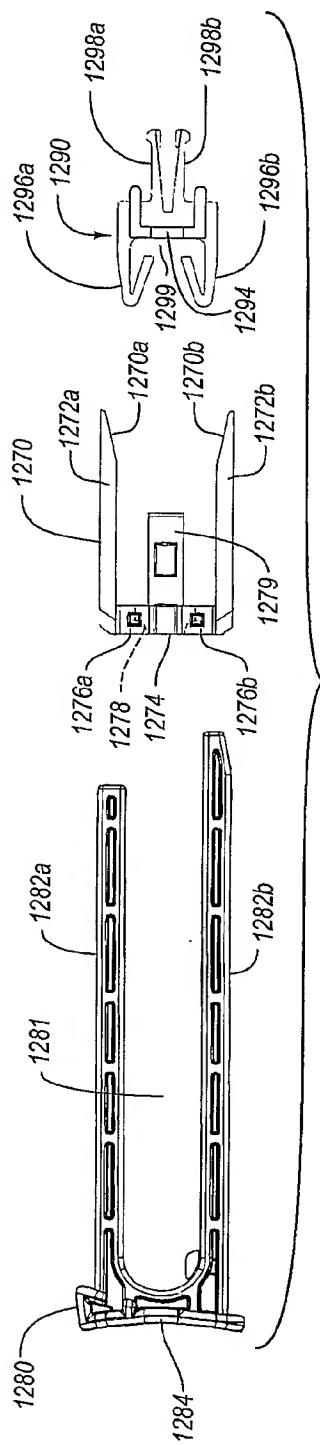


Fig. 11B

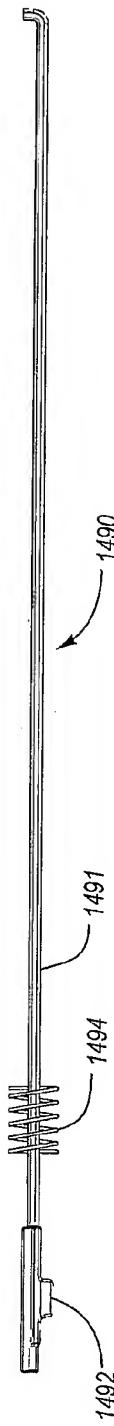


Fig. 11C

12 / 26

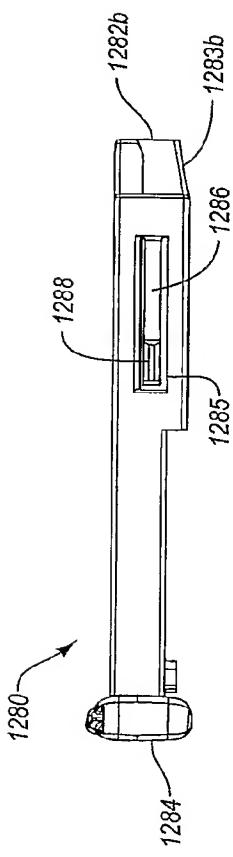


Fig. 11D

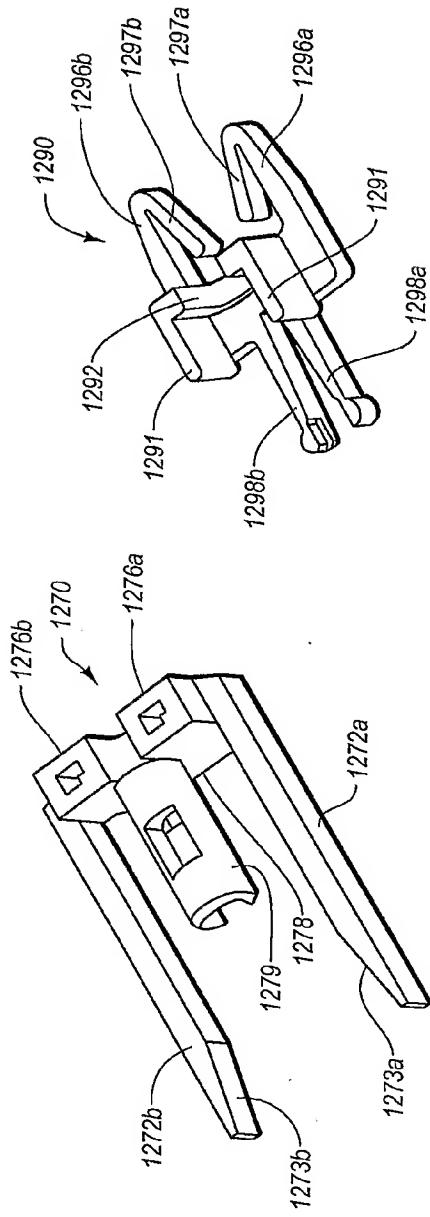


Fig. 11E

Fig. 11F

13/26

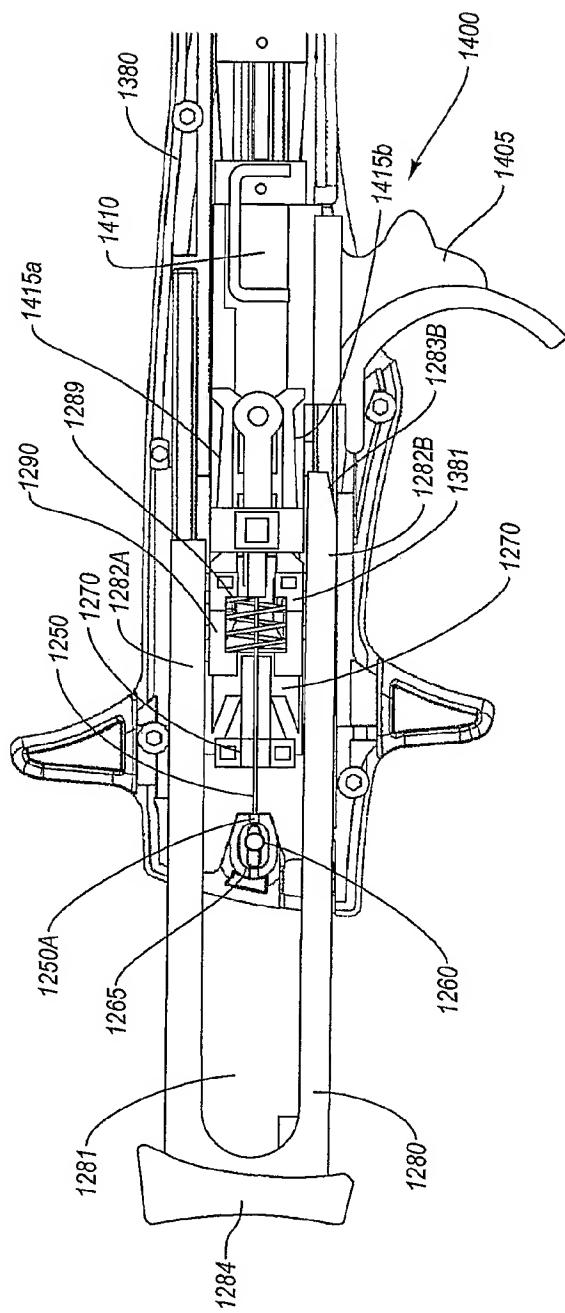
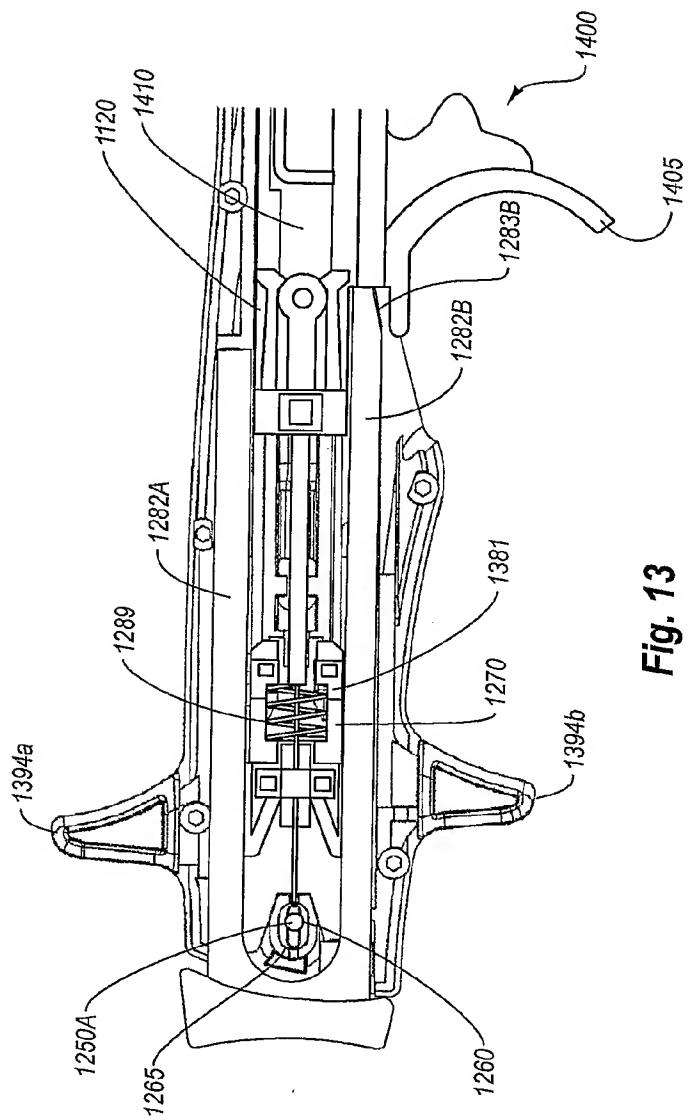


Fig. 12

14 / 26



15 / 26

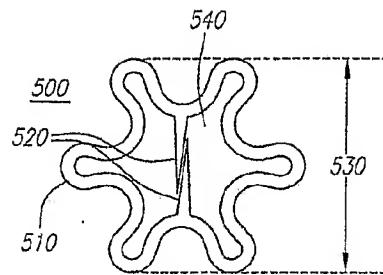


Fig. 14A

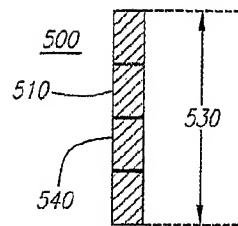


Fig. 14B

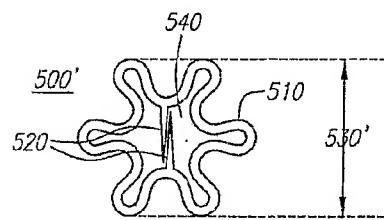


Fig. 14C

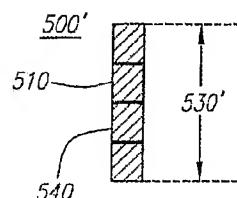


Fig. 14D

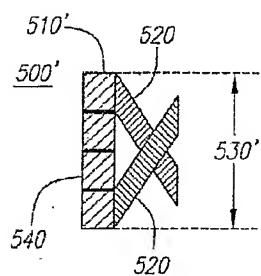


Fig. 14E

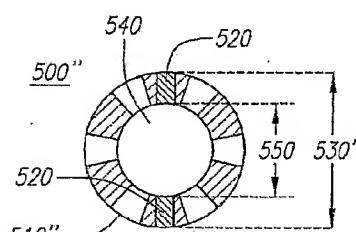


Fig. 14F

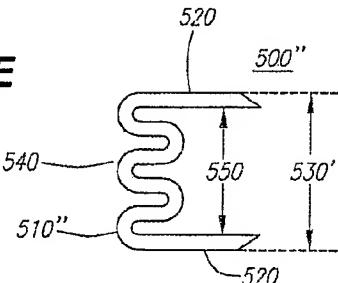


Fig. 14G

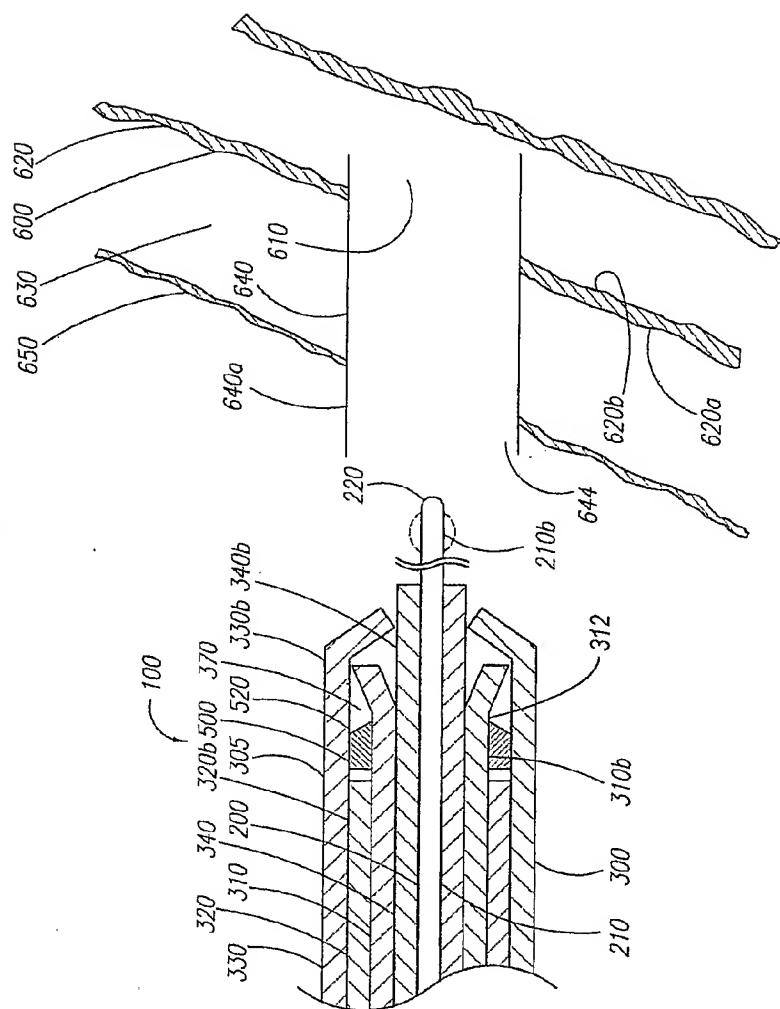


Fig. 15A

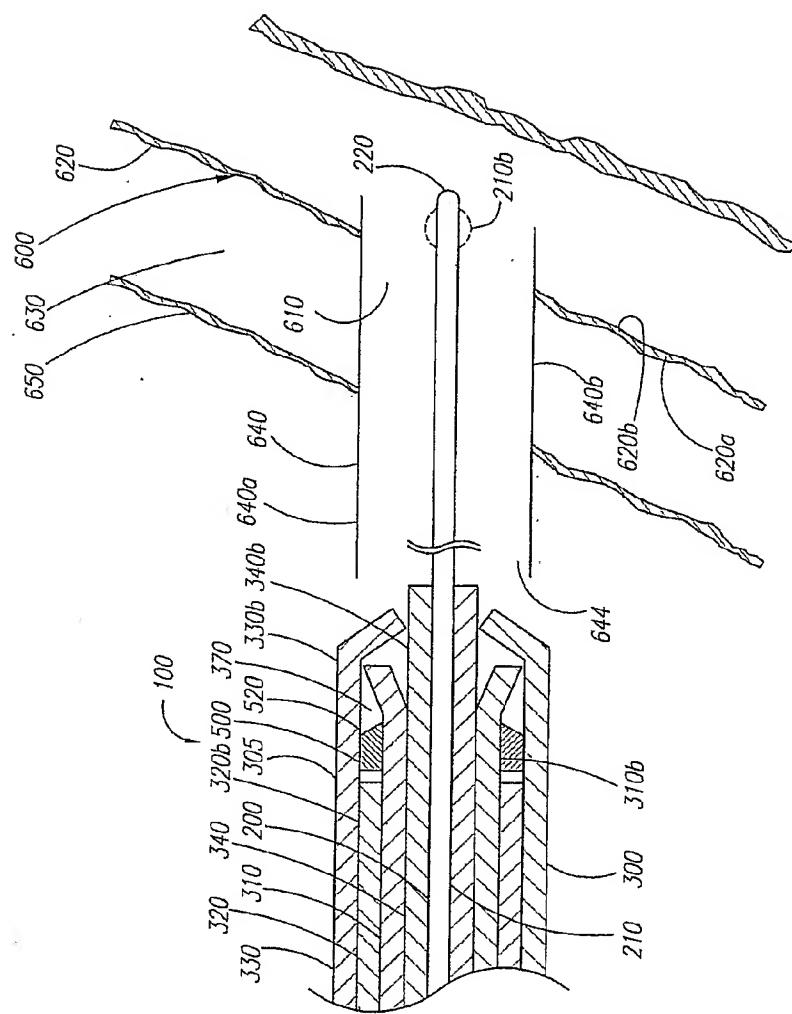


Fig. 15B

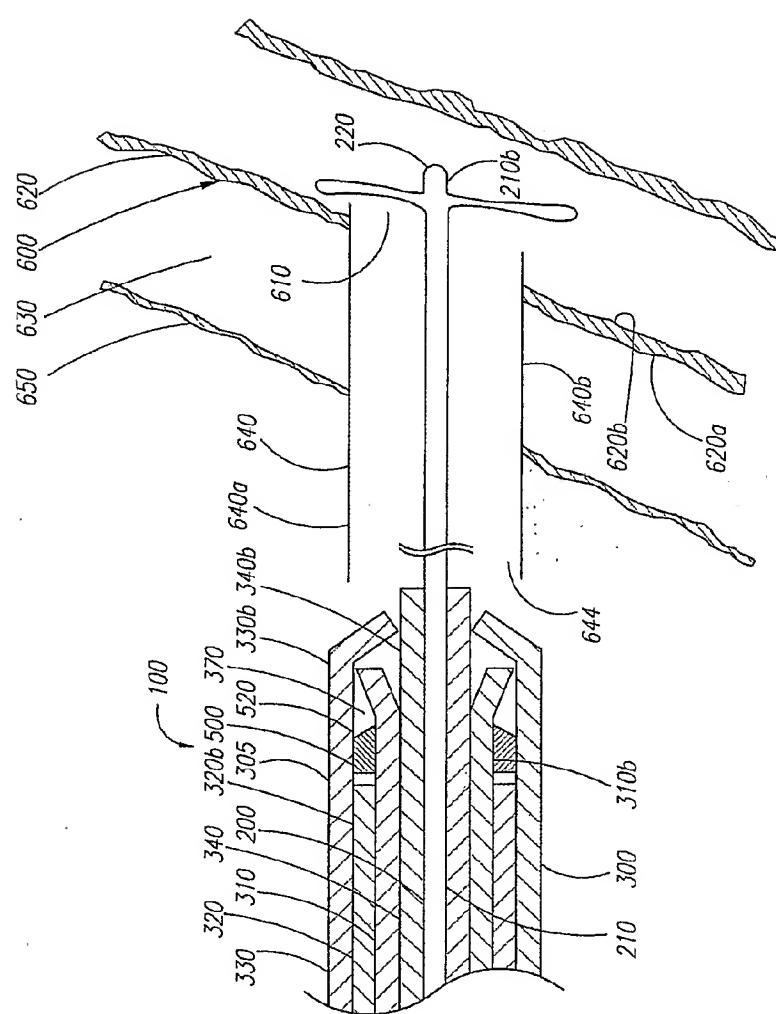


Fig. 15C

19 / 26

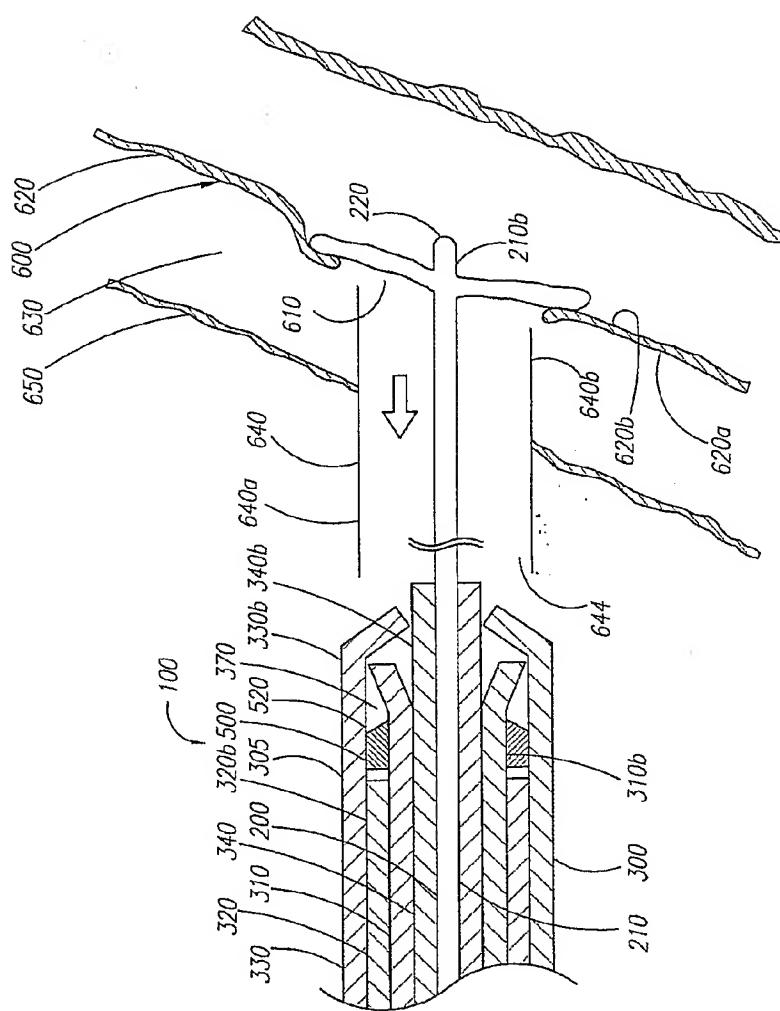


Fig. 15D

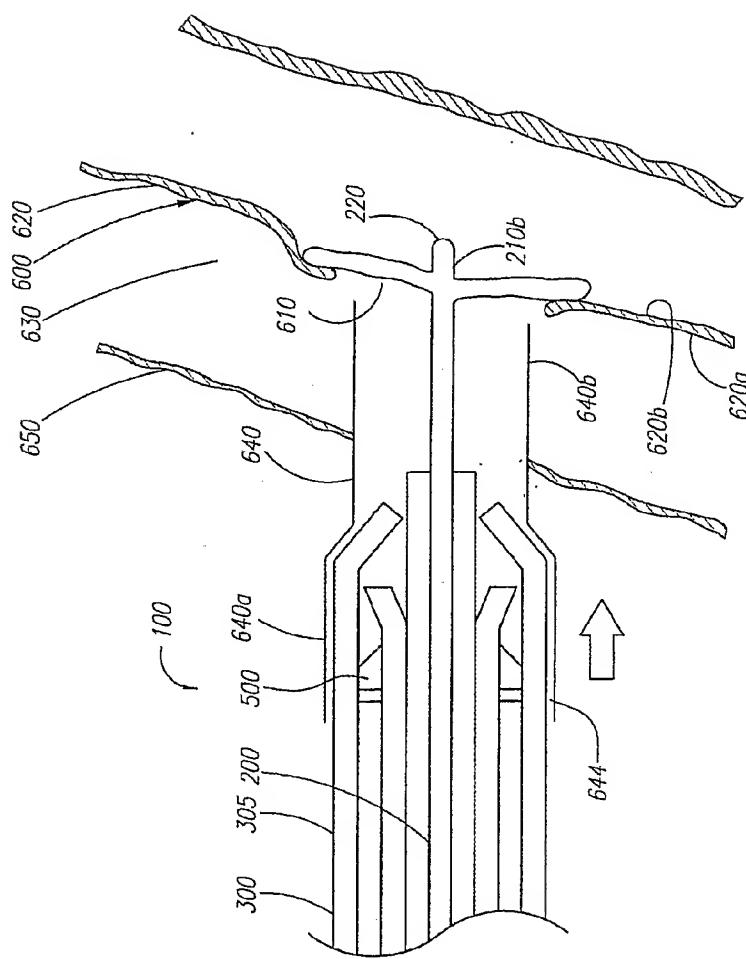


Fig. 15E

21 / 26

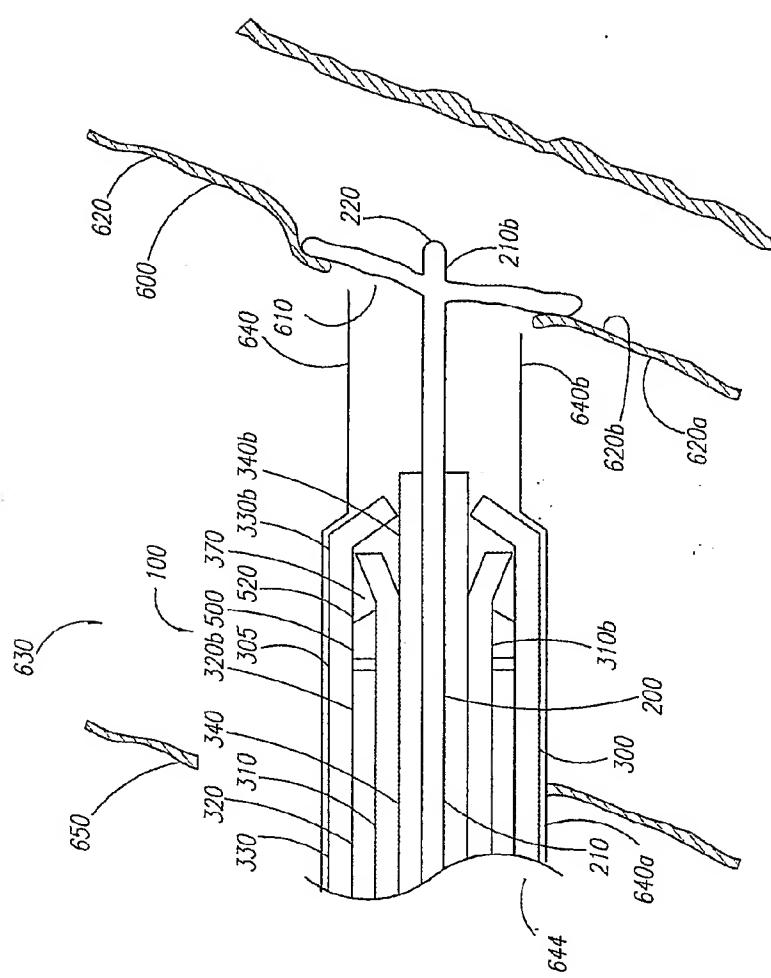


Fig. 15F

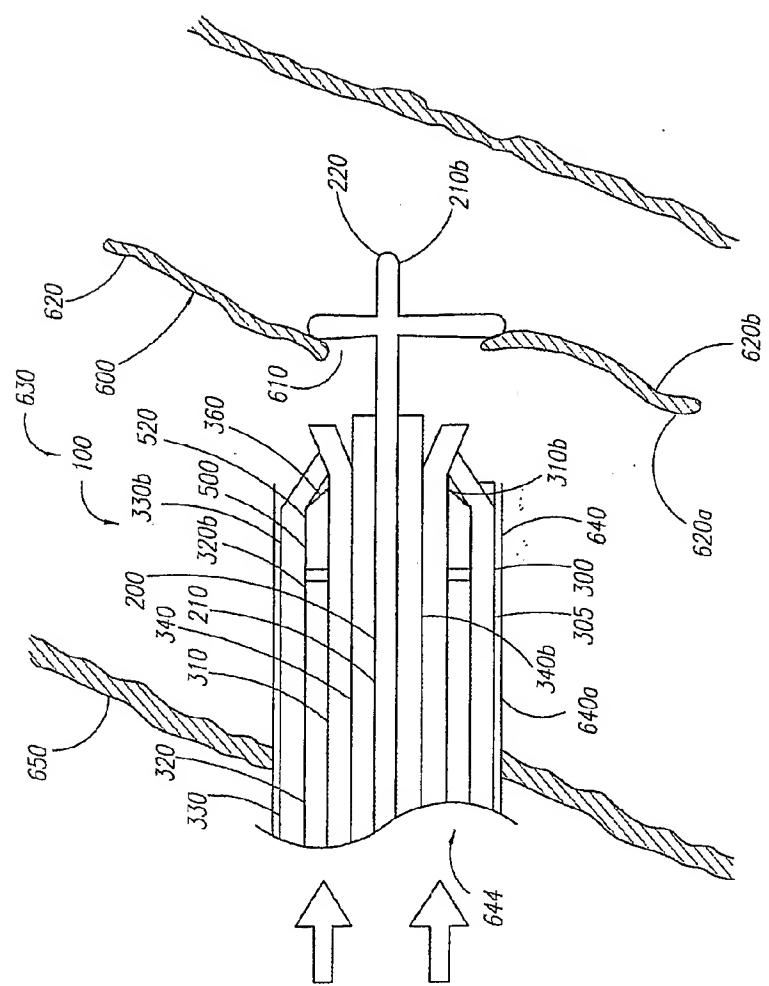


Fig. 15G

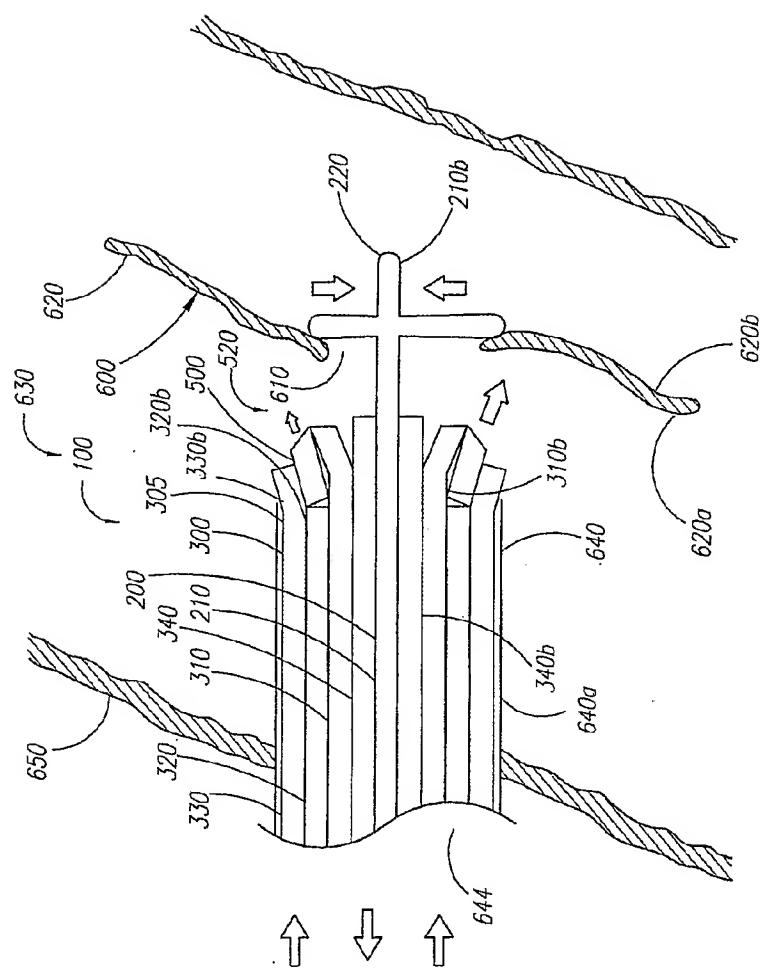


Fig. 15H

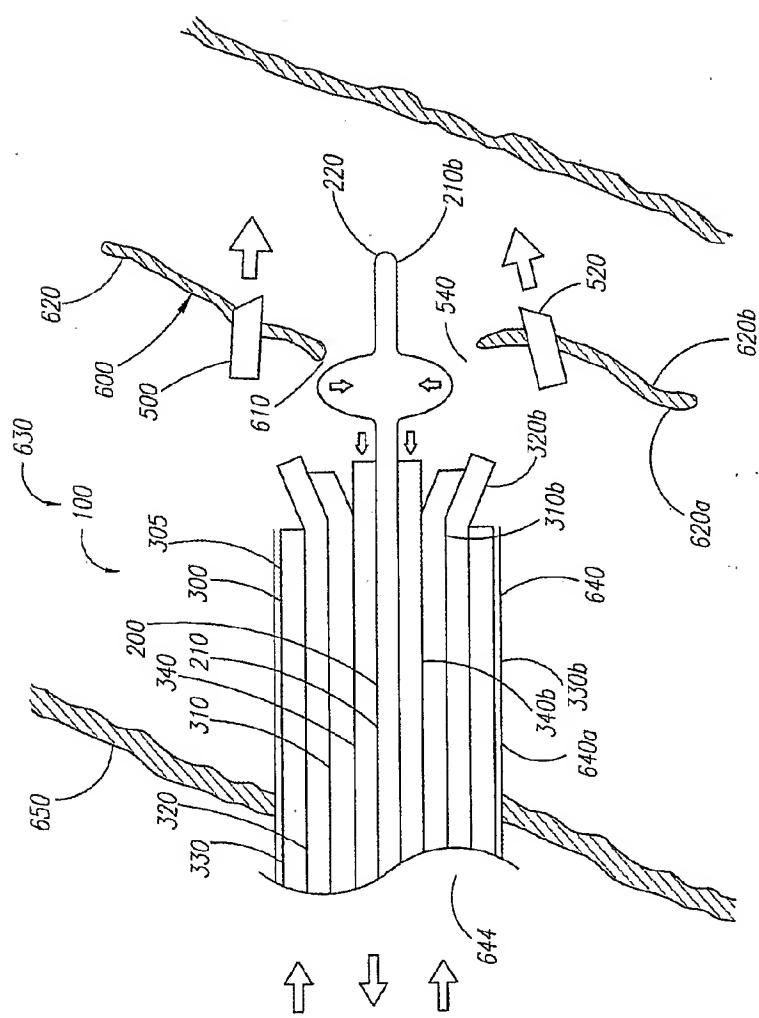


Fig. 15J

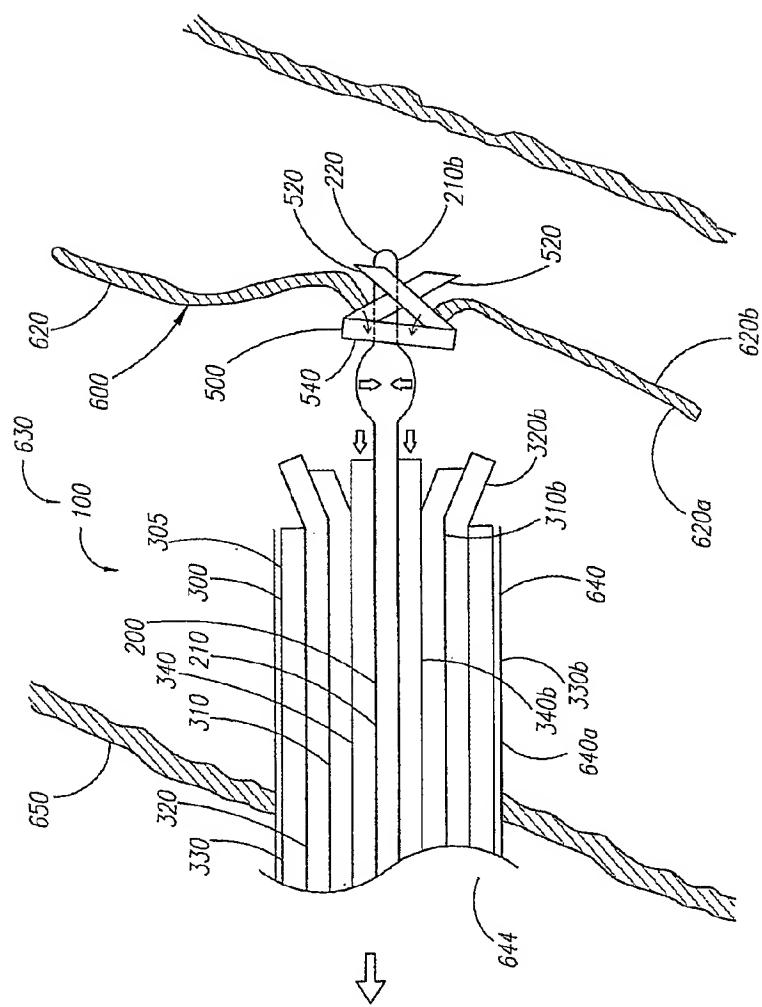


Fig. 15J

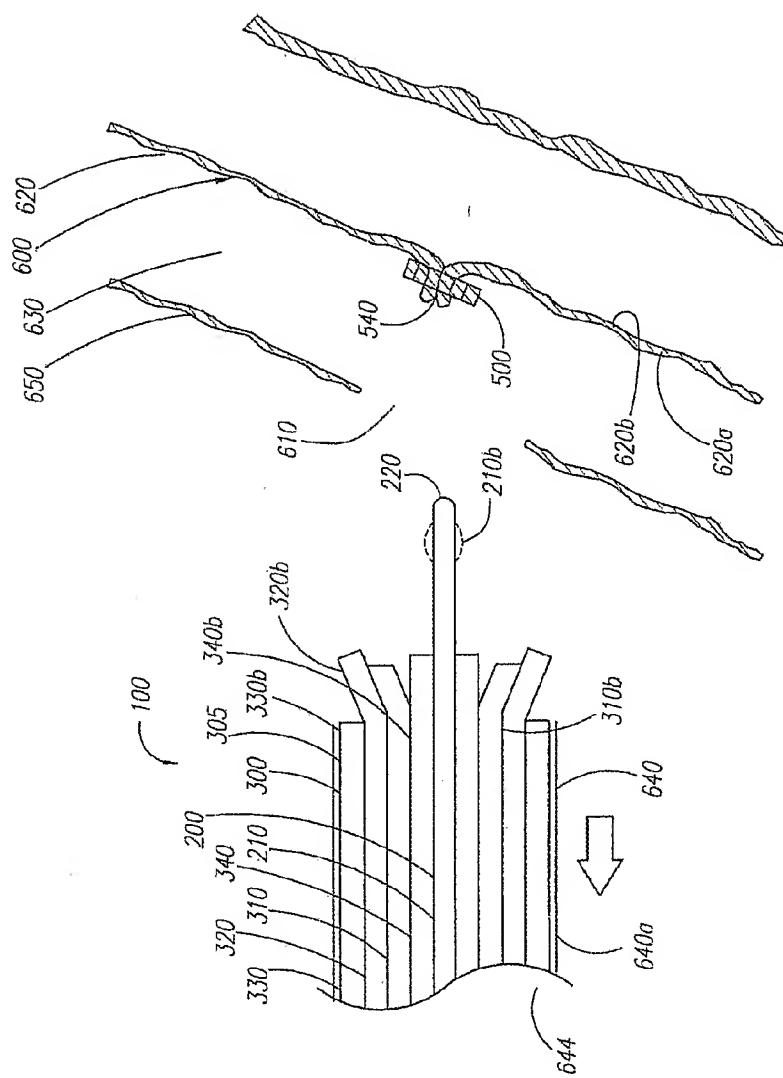


Fig. 15K

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
11 January 2007 (11.01.2007)

PCT

(10) International Publication Number
WO 2007/005585 A3

(51) International Patent Classification:

A61B 17/00 (2006.01)	A61B 17/064 (2006.01)
A61B 17/068 (2006.01)	A61B 17/122 (2006.01)

(21) International Application Number:

PCT/US2006/025538

(22) International Filing Date: 29 June 2006 (29.06.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/696,069	1 July 2005 (01.07.2005)	US
11/427,297	28 June 2006 (28.06.2006)	US

(71) Applicant (for all designated States except US): **ABBOTT LABORATORIES** [US/US]; 400 Saginaw Drive, Redwood City, CA 94063 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **WALBERG, Erik, K.** [US/US]; 1901 Terry Lane, Redwood City, CA 94061 (US). **REYNOLDS, Timothy, C.** [US/US]; 608 Conrado Terrace #3, Sunnyvale, CA 94085 (US). **ELLINGWOOD, Brian, A.** [US/US]; Po Box 60113, Sunnyvale, CA 95051 (US). **JAIR, Kai, Yenhai** [US/US]; 7100 Rainbow Drive #14, San Jose, CA 95129 (US). **PANTAGES, Anthony** [US/US]; 1839 Curtner Avenue, San Jose, CA 95124 (US).

(74) Agents: **RICHARDS, Jonathan, W.** et al.; **WORKMAN NYDEGGER**, 1000 EAGLE GATE TOWER, 60 East South Temple, Salt Lake City, UT 84111 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

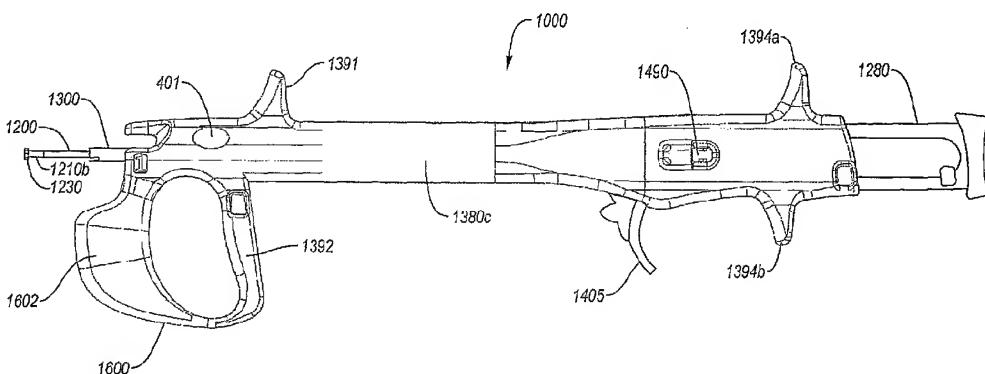
— with international search report

(88) Date of publication of the international search report:

3 May 2007

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: CLIP APPLIER AND METHOD OF USE



(57) Abstract: An apparatus for placement into an opening formed in a wall of a body lumen to deploy a closure element. The apparatus comprising a housing having a handle portion formed at a distal end, the handle portion configured to be engaged by a user when advancing the housing to deploy the closure element. A locator assembly and a carrier assembly are at least partially received in the housing. The locator assembly can have one or more expansion members that can selectively contact the wall of the body lumen and a proximal end configured to cooperate with a portion of a locator control system operable to expand the one or more expansion members. A triggering system cooperates with the locator assembly and is moveable toward the one or more expansion members of the locator assembly upon the locator control system being operated to expand the one or more expansion members.

WO 2007/005585 A3

INTERNATIONAL SEARCH REPORT

International application No	PCT/US2006/025538
------------------------------	-------------------

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/00 A61B17/068 A61B17/064
ADD. A61B17/122

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/069054 A2 (INTEGRATED VASCULAR SYSTEMS IN [US]; PALERMO THOMAS [US]; BELEF WILLIA) 19 August 2004 (2004-08-19)	1-4, 6-10, 12-18, 20-27
Y	page 29, paragraph 3 – paragraph 4 page 37, paragraph 3	11
Y	US 2 951 482 A (SULLIVAN GREGORY B) 6 September 1960 (1960-09-06) column 2, line 20 – line 34	11

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

6 February 2007

Date of mailing of the international search report

16/02/2007

Name and mailing address of the ISA/

European Patent Office, P.B. 5618 Patentlaan 2
NL – 2280 HV Rijswijk
Tel: (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Angeli, Markus

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/025538

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-7

Apparatus for delivering a closure element directed to an actuation mechanism comprising a movable plunger, a tubular body block and a tubular member slidably cooperating with each other for a reduction in travel of the trigger mechanism.

2. claims: 8-13

Apparatus for delivering a closure element directed to a handle portion for advanced handling.

3. claims: 14-27

Apparatus for delivering a closure element directed to a trigger extension for advancing a carrier.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2006/025538

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 2004069054	A2 19-08-2004	AT 333837 T	EP 1601292 A2	15-08-2006 07-12-2005
		US 2006020270 A1		26-01-2006
US 2951482	A 06-09-1960	NONE		